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Circuit for defibrillation waveform generation

Abstract

AED pulse generation circuits that provide floating, adjustable, bias voltages for driving a solid-state defibrillation waveform therapy generator circuit are provided. The provided bias voltages allow to reverse polarity of provided electric shock to increase chances of successful defibrillation and survival. In one of the provided configurations, energy stored in the pulse capacitor can be discharged by activating the waveform therapy generator in the high-resistance transconductance region. The circuits can be positioned on a self-contained module potted with an insulating material to reduce unintended interactions with other AED components. Through the use of the disclosed circuits, AED size can be reduced to promote pocketability while simultaneously increasing AED reliability.

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Background/Summary

FIELD

(1) This invention relates in general, to circuits for generating defibrillation waveforms and in particular, to a circuit for defibrillation waveform generation that increases AED reliability and decreases AED size.

BACKGROUND

(2) Sudden cardiac arrest (SCA) is a significant cause of mortality throughout the world and remains a major public health concern causing about 300,000 to 450,000 deaths each year in the United States alone, despite the broad scale teaching of cardiopulmonary resuscitation (CPR) and the implementation of public access automated external defibrillators (AED) in hospitals, ambulances and other public locations, like airports and stadiums. More than 9 of 10 SCA victims still die, even in locales with advanced medic response systems. In most rural locations,

the death rate approaches 100%.
(3) SCA occurs when the heart suddenly and unexpectedly stops pumping blood, most commonly caused by a chaotic cardiac rhythm disorder known as ventricular fibrillation (VF). VF is a lethal heart rhythm abnormality that causes the ventricles of the heart to quiver ineffectively, resulting in a failure to pump blood. Accordingly, blood pressure plummets and blood delivery to the brain and all bodily organs essential ceases in 5-10 seconds.
(4) SCA from VF constitutes the most time-critical emergency in medicine and is universally lethal within 10-20 minutes without prompt medical attention, specifically the delivery of a high-voltage, high-energy shock across the chest via a defibrillator, the only method known to stop VF. Preferably such a shock is delivered within 5 minutes of the onset of VF.
(5) Victims of VF collapse within 5-10 seconds, lose consciousness, and become unresponsive. Only someone that is physically near the victim has a meaningful chance at preventing death. The chance of survival rapidly decreases 7-10% per minute from onset of VF and, after 10 minutes, resuscitation rarely succeeds, even with CPR, and even if an AED is used, as the heart and brain will have suffered irreversible hypoxic injuries. Consequently, ensuring that people have immediate access to an AED is absolutely essential to saving lives from cardiac arrest, where every minute counts.
(6) AEDs made publicly available, however, have not meaningfully addressed the problem of SCA. By various accounts, there are approximately 3.2 to 4.5 million AEDs currently deployed in public places in the United States, yet an estimated more than 30 million AEDs are needed to provide sufficient coverage to meaningfully improve cardiac arrest survival rate nationally. Moreover, despite this disparity between the number of devices versus the estimated need, increasing the number of public access AEDs by an order of magnitude would be neither practical in terms of cost or execution nor would such an increase address the problem that SCAs primarily occur in places other than where public access AEDs are found. More than 70% of VF cases occur in or near the home or during routine activities of daily living, like yard-work and gardening, driving, personal recreation, and so on, locations where public access AEDs are not usually found. Immediate employment of an AED from time of victim collapse to shock delivery is optimal for survival, yet public access AEDs are rarely deployed or used in locations where SCAs typically happen and, if they are, their use often comes far too late. Thus, the problem of resuscitating victims from VF is inexorably linked to time and proximity to an AED, which are, in turn, inexorably linked to convenience of use, which is a direct consequence of AED cost, size and weight. Accordingly, to make a positive impact of survivability requires a different approach to AED deployment. One solution would be to provide AED devices that are pocket-sized and modest in weight and cost, so that AEDs become practically ubiquitous, similar to a mobile phone.
(7) The high cost and bulk of conventional public access AEDs are mainly due to the design choices of reusability, elimination of all possible failure modes, and telemetry functionality intended to constantly perform and transmit multi-use readiness checks. These typical AEDs perform self-testing constantly, which depletes the battery, and causes wear on the critical components, requiring large and complex circuit designs and components that will survive constant testing and the resulting high voltage bias that is induced. Several AED product recalls have shown this practice to prematurely degrade components, resulting in an AED becoming non-functional when needed. AEDs are typically designed to eliminate failure modes, which, paradoxically, results in large and complex custom components that are expensive and prone to failure. For example, conventional public access AED capacitors are often rated for use at temperatures of 90° C. and 20,000 discharges back-to-back, conditions that do not remotely resemble the typical use case under any conceivable scenario. Moreover, reusability requirements mean that the batteries must be able to store enough energy to defibrillate multiple patients, perform simulated use testing, as well as have a circuit able to sense when there is not enough energy to be “rescue ready” far in the future.
(8) These are key factors that effectively restrict deployment of public access AEDs only to healthcare providers, first responders, and public areas that are legally required to have an AED, all of which make existing AEDs relatively unavailable and of no use for the majority of VF emergencies that occur at or near the home away from public access AEDs. Moreover, public access AEDs are packaged in large carrying cases weighing several pounds that are too bulky to be convenient for ubiquitous use by the public. Furthermore, excluding costs of the perennial replacement of batteries and pads, AEDs typically cost at purchase between $1200 to $3500, which is too expensive for the average person to buy or to serve as an accessory to accompany activities of daily living.
(9) Further, in addition to the bulkiness of the current AEDs and their carrying cases, other components of public access AEDs further limit how small the AED can be made. In particular, typically such AEDs require a use of a transformer for generation of requisite defibrillation and control voltages. In particular, typical AEDs include a transformer with multiple windings that are used to generate bias voltages for high voltage pulse generation circuits. Such transformers tend to be large, usually at least a cubic inch of volume, thus increasing the size of the AED overall because of casing requirements. Further, the use of the transformers requires additional components

in the AED that are used to excite the transformer, rectify the transformer's output, and to provide regulation. Such components tend to use high voltages which have rigorous dielectric withstanding requirements and tend to be either bulky or prone to premature failure, especially when such components are miniaturized. This can often limit the lifespan of the AED overall. Further, the possibility of unintended conduction to other AED parts limits how such components can be placed and spaced thereby further increasing size, cost and the risk of malfunction.
(10) Therefore, a need remains for providing a new circuit design for rapidly generating high voltage therapeutic defibrillation waveforms that in turn facilitates the design of low cost and convenient pocket-sized AEDs. Such a design will also decrease the cost and bulk of conventional AEDs and defibrillation circuits in general, be they external or internal defibrillators.

SUMMARY

(11) AED pulse generation circuits that provide floating, adjustable, bias voltages for driving a solid-state defibrillation waveform therapy generator circuit are provided. The provided bias voltages optionally allows to reverse polarity of provided electric shock to increase chances of defibrillation success and survival that can occur in a subset of victims. In one of the provided configurations, unused energy intended for a shock to the patient can be discharged by activating the waveform therapy generator in the transconductance region utilizing a reduced gate voltage. The circuits can be positioned on a self-contained module potted with an insulating material to reduce unintended conductive interactions with other AED components. The use of such circuits reduces the complexity and component count present in traditional AEDs, thus decreasing size and cost of such AEDs while simultaneously improving their reliability.
(12) In one embodiment, a circuit for defibrillation waveform generation is provided. The circuit includes a sub-circuit that transmits energy through one of one or more isolation barriers; a further sub-circuit that transmits control signals through one of one or more of the isolation barriers; and one or more power generation sub-circuits that receive the energy through one or more of the isolation barriers to provide a floating, adjustable voltage to use as bias supply for a solid-state defibrillation waveform therapy generator circuit that is actuated by the control signals transmitted through the isolation barrier.
(13) In a further embodiment, a circuit for defibrillation waveform generation, is provided. The circuit includes a bias generation circuit, including: a switching regulator in buck configuration, wherein switched output of the regulator is connected to an input of a primary winding of a SMPS (switch mode power supply) transformer and wherein an output of the primary winding of the transformer is utilized to supply a regulated DC voltage which powers a microcontroller that is in control of a solid-state therapeutic defibrillation waveform generator; and one or more secondary windings of the transformer whose energy is rectified, wherein the rectified energy is used to supply one or more bias voltages to the solid-state therapeutic defibrillation waveform generator that is used to create a therapeutic defibrillation waveform.
(14) In a still further embodiment, a defibrillator utilizing a therapeutic defibrillation waveform generation circuit is provided. The defibrillator includes a bias generation circuit, including: a switching regulator in buck configuration, wherein the switched output of the regulator is connected to an input of a primary winding input of the transformer, wherein an output of the primary winding of the transformer is utilized to supply a regulated DC voltage to a microcontroller that is in control of a solid-state therapeutic defibrillation waveform generator; one or more of the secondary windings of the transformer whose energy is rectified; and the rectified energy is used to supply one or more bias voltages; and a solid-state defibrillation waveform generator that is configured to create a therapeutic defibrillation waveform utilizing one or more of the bias voltages.
(15) If significantly reducing the number of deaths from SCA due to VF is to be meaningfully addressed, which has been acknowledged as a problem for over 40 years, the design of conventional AEDs must change to lower cost and decrease size and weight, so that AEDs can be ubiquitously made available, including in every home and every car, as well as in many pockets and purses. Thus, by employing the described pulse generation circuits, the size and reliability of an AED can be meaningfully affected, therefore likely yielding an increased survival rate from cardiac arrest by virtue of its ease of availability because of its pocketability and its lower cost that allows large segments of the population to afford its purchase. This technology may also benefit size and cost reductions for wearable and implantable defibrillators as well as fully functional hospital-based defibrillators.
(16) Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) FIG. **1** is a process flow diagram showing, by way of example, a typical prior art use of a public access AED in an SCA situation.

(2) FIG. **2** is a block diagram showing functional components and a user interface for a disposable single use pocketable AED in accordance with one embodiment.

(3) FIG. **3** is a diagram showing of the pulse generation (discharge circuit) of FIG. **2** in accordance with one embodiment.

(4) FIG. **4** is a diagram showing of the pulse generation (discharge) circuit of FIG. **2** in accordance with a further embodiment.

(5) FIG. **5** is a diagram showing the pulse generation (discharge) circuit of FIG. **2** as well as portions of the charging circuit providing power to the MCU in accordance with a still further embodiment in which a buck fly configuration is utilized to provide power to the low-voltage digital electronics such as the MCU.

(6) FIG. **6** is a perspective view of an isolated module that includes the pulse generation circuit for use in the AED of FIG. **2** in accordance to one embodiment.

(7) FIG. **7** is a view of a top surface of the module of FIG. **6** in accordance with one embodiment.

(8) FIG. **8** is a bottom of the module of FIG. **6** in accordance with one embodiment.

(9) FIG. **9** is a flow chart showing a method for operating a disposable pocketable AED in accordance with one embodiment.

(10) FIG. **10** is a front view showing a disposable single use pocketable AED with dual free-floating electrodes in accordance with one embodiment.

(11) FIG. **11** is a cut-away view showing block component groups contained within the disposable single use pocketable AED of FIG. **10**.

(12) FIG. **12** is a side view showing the disposable single use pocketable AED of FIG. **10** with the housing and dual free-floating electrodes stowed in a carrying case.

(13) FIG. **13** is a side view showing the disposable single use pocketable AED of FIG. **10** with the housing and dual free-floating electrodes partially deployed from the carrying case.

(14) FIG. **14** is a back view showing the cable management system of the disposable single use pocketable AED of FIG. **10**.

(15) FIG. **15** is a front view showing a disposable single use pocketable AED with a single free-floating electrode in accordance with one embodiment.

(16) FIG. **16** is a rear view showing the integrated electrode of the disposable single use pocketable AED of FIG. **15**.

(17) FIG. **17** is a side view showing the disposable single use pocketable AED of FIG. **10** with the housing and single free-floating electrode stowed in a carrying case.

(18) FIG. **18** is a side view showing the disposable single use pocketable AED of FIG. **10** with the housing and single free-floating electrodes partially deployed from the carrying case.

(19) FIG. **19** is a top view diagram showing an electrode pad assembly for use in the disposable single use pocketable AEDs of FIGS. **10** and **15**.

DETAILED DESCRIPTION

(20) There has been a push to deploy public access AEDs in busy often-frequented places, such as airports, restaurants, casinos, shopping centers, and stadiums. Public access AEDs are relatively easy-to-operate devices for most trained responders that automatically diagnose whether VF (ventricular fibrillation) is present and, if so, urge delivery of defibrillation shocks by a bystander in an attempt to restore normal cardiac rhythm. FIG. **1** is a process flow diagram showing, by way of example, a typical prior art use of a public access AED **12** in an SCA situation. Public access AEDs are designed for repeated use by the general public and require minimal training to operate; users simply follow some combination of voice prompts, text prompts, or both, and diagrammatic instructions to deliver the defibrillation waveforms to SCA victims.

(21) In this example, a victim **18** has suffered suspected cardiac arrest while in the company of a rescuer **19**. The terms “victim” and “patient” are used interchangeably and refer to the individual that is receiving emergency care for a possible cardiac arrest. Similarly, the terms “rescuer,” “bystander” and “user” are used interchangeably and refer to the individual who is actively providing the emergency care through the use of a public access AED.

(22) When SCA is suspected, often when a victim suddenly loses consciousness and collapses, a rescuer **19** must take immediate action to assist the victim **18**, which begins by first locating and obtaining a public use AED **12** (step (1)) and calling 9-1-1. Note that there are two main categories of AEDs, either of which may be found in use as a public use AED. Some AEDs automatically deliver shocks without rescuer action when VF is detected. Most AEDs are semi-automatic and require the rescuer to manually trigger a shock with a button or device control. The portable AEDs carried by emergency medical services (EMS) personnel are generally designed as semi-automatic

AEDs that include physiological monitoring tools for both basic and advanced life support, as well as vital signs patient monitoring.

(23) A typical public access AED **12** is located where the general public ordinarily has access kept in some type of protective housing **10**, such as a display case, wall cabinet or kiosk. Public access AEDs are designed for long-term reuse and to be available to save multiple victims over their service lifetime, factors that add to unit cost and size, including maintenance obligations and telemetry functionality needed to prevent failures and sustain readiness over time. The public access AED **12** itself is portable and therefore susceptible to being misplaced or stolen; the protective housing **11** helps to keep the public access AED **12** secure and available until needed. Note that, despite being portable, a public access AED kit is bulky and weighs several pounds, which makes carrying a public access-type AED on an everyday basis impractical for most people, even though wider AED availability and use could help save more lives. In addition, both the electrodes and batteries of public access AEDs have expiration dates and must be replaced upon their respective expiry every one to three years. Moreover, these AEDs must undergo periodic operational testing that may require that the defibrillation circuit be energized, resulting in further depleting the battery and prematurely degrading the circuit.

(24) Returning to the steps of AED use in public, once the rescuer **19** locates and obtains an AED, the rescuer must activate the AED **12**, which generally entails pressing an “On” button or other controls (step (2)). Conventional public use AEDs **12** are packaged in a large carrying case that contains the AED circuit, including sensing and defibrillation circuit and battery, a pair of adhesive dermal electrode pads **17***a-b* connected by a set of leads **20**, and support accessories (not shown), such as gloves and a face shield. Electrode pads are generally about 8-12 cm in length, rectangular, and intended to conform to the human thoracic anatomy.

(25) As some rescuers will be lay bystanders, public use AEDs generally provide visual instructions **14** on assessing the victim's breathing and placement of its electrode pads **17***a-b* on the victim's chest **24** (step (3)). A note should be made however that many public rescuers are in fact medical personnel who take the initiative as a Good Samaritan. Nevertheless, the AED includes a set of necessarily simple controls, typically an “On” button **21** and, if the AED is semi-automatic, a “Shock” button **22** to manually deliver a defibrillation shock by the rescuer, plus a warning indicator **13** that the AED is charged and ready to deliver a defibrillation shock. To activate the public use AED **12**, the rescuer **19** simply presses the “On” button **21**. The visual instructions **14** are typically supplemented with speaker-generated voice prompts **15**, display-generated text prompts **16**, in some cases, an electrocardiogram (ECG) **23**, or some combination of voice prompts, text prompts and an ECG. The American Heart Association (AHA) and European Resuscitation Counsel (ERC) publishes guidelines outlining a recommended but not mandatory sequence of visual and voice prompts to help rescuers in proper use of AEDs. See, 2010 *American Heart Association Guidelines for CPR and ECC; Supplement to Circulation*, Vol. 192, Issue 18 (Nov. 12, 2010). *European Resuscitation Council Guidelines for Resuscitation* 2010, *Resuscitation* Volume 81 (October 2010).

(26) The paddles or electrode pads **17***a-b* must be applied by the rescuer **19** to be in direct contact with the victim's skin. Electrode pads are typically adhesive and, in many AED kits, a razor is included to shave hair off the victim's skin, if needed, on the anatomy where electrode pads are to be placed. To maximize the transit of current through the heart, an anterior-lateral position for electrode pad placement on the victim's chest **24** is preferred. The anterior pad is applied on the right anterior upper chest **24** just below the right clavicle. The lateral pad is applied immediately below and lateral to the left nipple. In female patients, the lateral pad should be applied on the chest wall below and lateral to the left breast, and not over the breast tissue.

(27) With the pads in place, the typical traditionally AED commonly in use will determine if a shockable rhythm is present depending upon the ECG obtained from the pads and instruct the rescuer to deliver a defibrillation shock, if required, to stop VF and allow the heart to reestablish an effective normal rhythm. If the public use AED **12** is semi-automatic, the rescuer **19** will need to manually administer the shock by pressing the “Shock” button **22**. At times, traditionally, multiple shocks may be required whereupon rhythm analysis by the AED (step (4)) dictates the timing of recurrent defibrillation shocks. Resuscitation of the victim **18** is unlikely if defibrillation is unsuccessful and/or is delivered too late. Some AEDs provide for escalating energy delivery when a previous shock attempt fails to terminate VF as determined by the ECG. Higher energy delivery may or may not restart the heart, but also more likely to cause temporary damage to cardiac tissue. Further, AEDs with higher shock energies also result in increased weight and cost of the AED minimizing its portability and broad availability and have been well demonstrated to not be required in the early rescue process to terminate ventricular fibrillation.

(28) Moreover, public access AEDs are designed and built to save multiple victims over the service life of the device despite long periods of idle standby storage. These requirements lead to a complex, large, and typically over-engineered design, which also leads to high cost and long-term maintenance obligations. The design and construction of public use AEDs uses large heavy batteries and costly electronic components intended to ensure operability when and if the AED is needed for use. And yet, such costly designs often fail because of their

complexity.
(29) As public use AEDs are big and bulky, they are ordinarily only going to be found in a stationary place in a controlled access protective housing, which inherently limits their availability during a SCA emergency and, to a large extent, renders public use AEDs largely ineffective in reducing the number of deaths caused by most SCA deaths that occur in the private settings of the home. Public use-type AEDs are also expensive and seldom found outside of areas where their placement is legally required given the significant economic burden associated with both initial acquisition and ongoing maintenance costs that often exceed the initial price of the AED. Thus, even though most SCAs occur in the home, AEDs are seldom found there, or in countless other random places where people often suffer a SCA, such as in cars and private boats, in parks or trails where people are walking, exercising or enjoying the outdoors, and where people are visiting with friends, and so forth. Despite being portable, the size and weight of a full public use AED kit makes carrying one personally in a backpack or stowed in the glove box of a car impractical.
(30) Conventional AEDs are battery powered and include a charging circuit that uses a step-up transformer to increase battery voltage from low voltage in the range of 6-24 volts (V) to around 1000-6000 V (note that higher voltages are rarely used today), a rectification circuit to convert the high voltage AC energy from the step-up transformer to direct current (DC) energy, and a pulse capacitor to store the energy prior to defibrillation shock delivery. These traditional pulse capacitors are rated to handle high voltage and large sudden discharge currents; as a result, they can be difficult to manufacture and are prone to failure, thereby increasing associated costs. Once this type of legacy pulse capacitor is charged, the AED is ready to deliver a defibrillation shock and the charging circuit switches the energy to the patient, whereby the current is delivered to the victim's chest to complete the circuit. For successful defibrillation, the current delivery waveform must be physiologically appropriate.
(31) Current commercially available AEDs generally employ biphasic truncated exponential (BTE), pulsed biphasic, or rectilinear biphasic waveforms. In contrast to the historical use of monophasic waveforms, properly designed biphasic waveforms are both more effective and require less energy for defibrillation. Accordingly, monophasic waveforms are no longer used. With a biphasic defibrillator, the initial energy level for defibrillation typically begins at 120 J (although it can be less) and can escalate for the second and subsequent defibrillation shocks up to a maximum of 360 J. Energy choice and escalation are waveform- and manufacturer-specific.
(32) This historical background of the status quo notwithstanding, the life-saving benefits of AEDs can be more efficaciously provided to every person, everywhere and on a **24**/**7**/**365** basis through a disposable, single-use AED that is small enough to be truly portable, for instance by fitting in an average-sized pocket. A single use AED, that is, a device that is available to therapeutically treat one instance of SCA, significantly streamlines and simplifies the design requirements of the AED and accordingly makes it possible to house the AED in a small pocketable form factor. Periodic maintenance is not required, as the disposable nature of the pocket AED implies the device will be discarded before needing to undergo maintenance or other testing prior to use on a patient. As well, the failure ratings of the electronic components need only accommodate one use, rather than repeated uses over an extended service life of many years, limiting complexity and improving durability. Similarly, the battery can be smaller and lighter, as battery life will not be depleted by long shelf life and telemetry transmissions related to diagnostic routines and maintenance test cycles. Further, the use of such simplified electronic components and battery technologies lowers cost and allows disposability to be realized. Finally, to encourage being carried by users at all times, the pocket AED is sized comparably to a conventional smartphone, for instance, in the range of 2.25 to 3.5 inches wide, 5.25 to 7 inches long, and 0.25 to 1.5 inches thick, and of similar weight, for example, in the range of 130 to 550 grams.
(33) To facilitate the construction of a disposable pocketable AED to fit into a small form factor, various charging configurations are provided. FIG. **2** is a block diagram showing functional components and a user interface **72** for a disposable pocketable AED. For the sake of clarity, only the defibrillation circuit **70** will be discussed in detail.
(34) The defibrillation circuit **70** includes components for providing a basic user interface **72** that includes an “On” switch (not shown), a “Power On Indicator” **75**, a charging indicator **76**, and optionally, a warning indicator **77** that indicates defibrillation shock delivery readiness with attendant dangers of exposure to high voltage, plus an optional speaker **78** through which audible instructions can be played. The user interface **72** also includes a visual display (not shown) on which text prompts can be displayed. In one embodiment, an AED incorporating the defibrillation circuit **70** can be semi-automatic and require the rescuer to manually trigger a shock by actuating the charging indicator **76**; in a further embodiment, an AED incorporating the defibrillation circuit **70** employs a circuit to automatically deliver the defibrillation shock to the victim without user action once the pulse generation circuit **88** is ready, that is, the pulse capacitor **81***b* is charged by a high voltage charger circuit **81***a* and is ready to provide power to a solid-state defibrillation waveform therapy generator **406**, and after the user has been warned to avoid any direct physical contact with the patient during shock delivery.
(35) The defibrillation circuit **70** is controlled by a microcontroller unit (MCU) **71** or system-on-chip controller

(SoC) (not shown) that is micro programmable, which allows updated controller firmware to be downloaded from an external programmer into a persistent memory store. Sensing circuit **87** is connected in line with the inputs and outputs of a discharge and polarity control circuit **82**. The sensing circuit **87** determines whether a shockable rhythm is present and monitors for the MCU **71** the defibrillation energy that is received from the pulse capacitor **81***b* as an input to the discharge and polarity control circuit **82** and the defibrillation waveform or "pulse" that is output. ECG front end circuit **74** evaluates heart rhythm for the MCU **71**. The ECG front end circuit **74** taps off the leads **86***a-b* of the pair of electrode pads **85***a-b* to sense cardiac signals, while the sensing circuit **87** taps off the discharge and polarity control module's input leads to monitor the shock delivery process. The sensing circuit **87** is implemented through conventional VF detection algorithms to detect the presence of a shockable rhythm, such as published by A. Fan, et al., Shockable Rhythm Detection Algorithms for Electrocardiogram in Automated Defibrillators, AASRI Conf. on Comp. Intel. and Bioinfor. pp. 21-26 (2012). The ECG front end circuit **74** is implemented through conventional heart function evaluation algorithms, such as provided through the ADS1x9xECG-FE family of integrated analog front-end ECG circuits, available from Texas Instruments, Dallas, TX. Other types and configurations of sensing and ECG front end circuitries are possible.

(36) When a shockable rhythm is detected, based on inputs from the sensing circuit **87** and the ECG front end circuit **74**, the MCU **71** determines the parameters of a defibrillation waveform in terms of energy, voltage, and pulse width; the defibrillation waveform is algorithmically selected based on the nature of the shockable rhythm to be medically appropriate for restoring normal cardiac rhythm. Up to a maximum of three shocks may be needed if the victim fails to be resuscitated, after which further shocks are generally futile.

(37) In response to the sensing circuit **87** determining that a shockable rhythm is still present after initial shock delivery, that is, defibrillation failed to establish normal cardiac rhythm, the MCU **71** may simply repeat the delivery of the defibrillation pulse or, if appropriate, revise the parameters of the defibrillation waveforms for the subsequent pulses. In this situation, subsequent defibrillation shocks may need to be escalated for the second and subsequent defibrillation shocks, generally up to a maximum of 360 J. In a further embodiment, parameters consisting of one or more of energy, voltage and pulse width are adjusted by the MCU **71** in real time, as further discussed infra with reference to FIG. **9**.

(38) Defibrillation energy is generated and stored as part of a pulse generation circuit **88** (also referred to as a waveform generator **88**) that includes multiple power generation sub-circuits. FIG. **3** is a diagram showing Waveform Generator **88 88** of FIG. **2** in accordance with one embodiment. The power generation sub-circuits **405***a-b* provide a floating bias voltage where **405***c* provides a floating, adjustable voltage that is used as a bias supply for a solid-state defibrillation waveform therapy generator circuit **406** that generates the defibrillation shock provided to the patient through the pads **85***a*, **85***b* (also referred to as electrodes **85***a*, **85***b*). In particular, the solid-state defibrillation waveform therapy generator circuit **406** includes multiple solid-state switching elements **407***a-d* whose output, when combined, determines the polarity of the defibrillation waveforms delivering the shock. In one embodiment, the solid-state defibrillation waveform therapy generator **406** can be in the form of an H-Bridge while the elements **407***a-d* can be one or more of a field-effect transistors (FETs), and one or more silicon-controlled rectifiers (SCRs), triode for alternating current (TRIAC), a bipolar junction transistors (BJTs) or a combination of one or more of the different types of elements **407***a-d*. The components with an insulated gate can in turn can include one or more insulated-gate bipolar transistors (IGBTs) one or more Silicon Carbide FETs, though other types of FETs are also possible. Still other types of elements **407***a-d* are possible. In one embodiment, the solid-state defibrillation waveform therapy generator circuit **406** can be MMIX4B22N30 High Voltage, High Gain BIMOSFET™ Monolithic Bipolar MOS Transistor sold by IXYS Corporation of Milpitas, California, though other types of the solid-state defibrillation waveform therapy generator **406** switching components **407***a-d* are also possible.

(39) As further described below, the polarity of the defibrillation shock delivered by the solid-state defibrillation waveform therapy generator **406** can be inverted through controlling the floating, optionally adjustable voltage that is delivered to each of the solid-state switching elements **407***a-d*. By controlling which of the elements **407***a-d* are open and closed during the delivery of a particular shock, individually or in unison, the polarity of the shock (i.e. which of the electrodes **85***a*, **85***b* as the anode during the delivery of the shock) is also controlled.

(40) The power generation sub-circuits **405***a-c* are electrically isolated from each other and provide both the free floating, bias voltage and control signals to the elements **407***a-d*. In particular, each sub-circuit **405***a-c* includes at least two domains that are separated by one or more isolation barriers, with each domain having a bias voltage ground reference that is independent of the ground reference in the other domain and the ground references between the domains being different. The sub-circuits **405***a-c* receives energy (also referred to as power in the description below) from the battery **83** and control signals from the MCU **71** via the pins **401**, **402**, **403** and **409** respectively in one of the domains, and pass the control signals and the power through the one or more isolation barriers from one domain to another domain. The power and control signals can be transmitted through the one or

more isolation barriers in a variety of ways, such as by modulating power transmission and the control signals through an isolated power transmission circuit, by utilizing alternating magnetic fields, by utilizing capacitive coupling, by utilizing optical coupling, by utilizing radiofrequency (RF) coupling, or a combination of one or more of these techniques. Still other ways to transmit the power and control signals through the one or more isolation barriers are also possible. The pin **404** is used to control the bias voltage of switching components **407***c* and **407***d*. When driven low, a regulator (**408**) decreases the floating bias voltage resulting in elements **407***c* and **407***d* operating in a high resistance transconductance region. When operating in this region, the residual energy stored in the pulse capacitor **81***b* may be safely shunted internally by activating elements **407***a* and **407***c* or elements **407***b* and **407***d*.

(41) By passing through the one or more isolation barriers, the power received from the battery **83** (via the switch **84**) is coupled through charge injection to achieve the free floating, adjustable bias voltage that can be used for driving one (or two in the case of the sub-circuit **405***c*) of the solid-state switching elements **407**. In one embodiment, the sub-circuits **405***a-c* can be TPSI3052 Isolated Switch Driver with Integrated 15-V Gate Supply sold by Texas Instruments Incorporated of Dallas, Texas, though other kinds of sub-circuits **405***a-c* are possible. For example, the sub-circuits **405***a-c* can be AHV85110 “Self-Powered Single-Channel Isolated GaN FET Gate Driver with Power-Thru Integrated Isolated Bias Supply” distributed by Allegro Microsystems of Manchester, NH, though other kinds of sub-circuits **405***a-c* are also possible.

(42) The sub-circuits **405***a* drives only the element **407***a* and the sub-circuit **405***b* drives only the element **407***b* due to the elements **407***a-b* being interfaced to the patient through one of the electrodes **85***a*, **85***b* and thus requiring separate ground references. However, the elements **407***c* and **407***d* can share a common ground reference; these elements, **407***a, b*, are provided a reference by only a single sub-circuit **405***c*, allowing to reduce space required by the charge circuit **88**.

(43) The bias voltage generated by the sub-circuit **405***c* is in turn regulated by a linear regulator **408** as low voltage may be required to operate ports of the waveform generator **406** in the transconductance region. In one embodiment, the linear regulator **408** can be NCV8730ASNADJTIG linear regulator sold by Semiconductor Components Industries, LLC dba ONSEMI of Scottsdale Arizona, though other linear regulators are also possible. The linear regulator **408** is in turn interfaced to two gate drivers **409***a*, **409***b*. The gate driver **409***a* is interfaced to the pin **402** and provides the regulated bias voltage or ground to the element **407***c*. The gate driver **409***b* is interfaced to the pin **403** and provides the regulated voltage to the element **407***d*. Through the gate drivers **409***a, b*, the sub-circuit **405***c* can drive the elements **407***c* and **407***d* independently of each other.

(44) The use of the independent, isolated sub-circuits **405***a-c* to independently generate a bias voltage for the elements **407***a-d* avoids including a bias generation transformer as part of the pulse generation circuit **88**, thus allowing a decrease in the size and an increase in the reliability of the AED overall. Further, the use of the independent, isolated sub-circuits **405***a-c* allows the power generation circuitry to be distributed in advantageous locations simplifying routing of the AED. When energy is stored in the pulse capacitor (**81***b*), but the energy is not delivered (for example spontaneous restart of the heart's normal rhythm), the energy stored in the capacitor needs to be discharged safely. Conventionally, such stored energy is discharged through a dedicated discharge circuit consisting of a resistor, inductor or resistor with an inductor in series, which adds volume, weight and cost to the AED while greatly reducing reliability. The pulse generation circuit **88** of FIG. **3** is able to discharge the stored energy without a dedicated discharge circuit by activating the solid-state defibrillation waveform therapy generator **406** elements **407***a* and **407***c* or element **407***b* and **407***d* in the transconductance region. The activation in the transconductance region allows the solid-state defibrillation waveform therapy generator **406** to safely transform the power absorbed by the switching elements **407***c* and **407***d* into heat and thus safely discharge the energy stored in the pulse capacitor **81***b* initially charged for delivering the defibrillation shock that is no longer needed because of spontaneous restoration of a normal cardiac rhythm. Other reasons for which the discharge of the pulse capacitor **81***b* may be needed can include: the defibrillator being off; the defibrillator running out of battery and not being able complete another shock (with making a prediction regarding sufficient power being in the battery not being possible to predict in certain circumstances before charging the capacitor); the defibrillator having an irrecoverable failure; a defibrillator malfunction being detected; an unsafe leakage current being detected; patient safety reasons; service reasons; the capacitor having been charged for too long; and the shock being aborted for any reason, though still other reasons are possible. When discharging the energy, the gate voltage at which the power is provided to the solid-state defibrillation waveform therapy generator **406** is lower than the voltage at which the power is provided to the generator **406** for generating the defibrillation shock to reduce the amount of heat that is generated over a period of time (by running the h-bridge **406** in the saturated region). The reduction in the voltage is accomplished using the voltage regulator (**408**) controlled by the isolated driver portion of subcircuit **405***c*. In one embodiment, all pairs of elements **407***a-d* of the generator **407** could be activated sequentially one or more times to discharge the prepared energy through heat. For example, at first the

elements **407***a* and **407***c* could be activated at the same time, and then after a pause to allow the generated heat to dissipate, the elements **407***b* and **407***d* could be generated one after another, with a pause being made between the activations to allow the generated heat to dissipate. Other sequences of activation are also possible. While the waveform generator **88** is operated in the transconductance region, the MCU **71** controls the waveform generator **88** to shunt energy provided to the generator **88**.

(45) In a further embodiment, the functionality of the sub-circuits **405***a-c* could be integrated into a single circuit. FIG. **4** is a diagram showing of the pulse generation circuit **88** of FIG. **2** in accordance with a further embodiment. In the embodiment accordingly shown with reference to FIG. **4**, four sub-circuits **405***e-h* that are structurally and functionally equivalent to the sub-circuits **405***a-c* of FIG. **3** are integrated into a single circuit **411** that is connected to the four pins **401**-**403**, **409** and that provides the free floating, adjustable bias voltage and control signals that drive the solid-state switching elements **407***a-d* of the solid-state defibrillation waveform therapy generator **406** in the same way as described above with reference to FIG. **3**. The solid-state defibrillation waveform therapy generator **406** and the elements **407***a-d* can be the same as described above with reference to FIG. **3**. As generating the low voltage necessary for activating the solid-state defibrillation waveform therapy generator **406** in the transconductance region, a custom ASIC may be employed for an integrated solution, or the output voltages of **405***c-h* may be downregulated through the use of a linear regulator or other voltage reducing circuit. The pulse generation circuit **88** in the embodiment of FIG. **4** may optionally include a dedicated discharge circuit (not shown) that is interfaced to the pulse capacitor (**81***b*) and that includes a resistor through which energy accumulated for delivering a defibrillation shock that was not delivered to the patient can be discharged.

(46) In a still further embodiment, the pulse generation circuit **88** can utilize a buck-fly topology for generation of multiple bias voltages that drive the solid-state defibrillation waveform therapy generator **406**. FIG. **5** is a diagram showing of the pulse generation circuit **88** of FIG. **2** in accordance with a still further embodiment in which a buck-fly configuration is utilized. In the embodiment shown with reference to FIG. **5**, the pulse generation circuit **88** includes a switching regulator **421** in buck configuration. In one embodiment, the switching regulator **421** can be a switching controller with an integrated switching element, or a switching controller with an external switching device such as a FET, though other kinds of switching regulators are also possible. The switching regulator **421** is interfaced to a transformer **425** that has a primary winding **422** and one or more secondary windings **423***a-c*.

(47) The switching regulator **421** is connected to an input of a primary winding **422** and the switched output of the switching regulator **421** is provided to the input of the primary winding **422**. The primary winding **422** acts as an inductor in a DC-DC convertor configuration. Secondary isolated voltages are scavenged by secondary bias windings **500***a*, **500***b*, **500***c*. During off time, the input of the primary winding **422** is protected by an element such as a free-wheeling diode **426** (or alternatively by using a regulator that features a synchronous rectifier) that provides a current return path that keeps the voltage on the primary winding from **421** going too high when LX (switch pin of the switching regulator **411**) is an open circuit (presuming the switching regulator chosen is not of the synchronous type). Further, the output of the primary winding **421** is utilized to supply a regulated DC voltage which powers the low-voltage digital circuitry such as the MCU **71** controlling the solid-state therapeutic defibrillation waveform generator **406** and optionally other parts of the AED.

(48) The transformer **425** is a step-up transformer and there is an increase in the voltage between the primary and secondary windings **423***a-c*. The output of the transformer **425** is also provided through the secondary windings **423***a-c* that is rectified and then used to drive the elements **407***a-d* of the solid-state defibrillation waveform therapy generator **406**.

(49) Before reaching the elements **407***a-d*, the output of the secondary windings **423***a-c* is converted to a DC voltage by a rectifier. The rectifier can be a rectifier diode **428**, a bridge rectifier, or a synchronous rectifier, though other kinds of a rectifiers are also possible. Further, after passing through the rectifier, the bias voltages from each of the secondary windings **423***a-c* passes through one or more drivers **431** that switch the bias voltage and in turn each deliver the switches bias voltage to one of the elements **407***a-d*. The four pre-drivers include two high-side pre-drivers and two low-side pre-drivers, with the four pre-drivers driving the four elements **407***a-d* of the waveform generator **406**. Similarly to what is described above, by individually actuating the elements **407***a-d*, the polarity of the waveforms delivered by the waveform generator **406** can be reversed under control of the MCU **71** if previously delivered shocks of opposite polarity do not achieve termination of the victim's ventricular fibrillation. While the drivers **431** are referred to as IGBT drivers **431** with reference to FIG. **5**, when the elements **407***a-d* are other than IGBTs, the drivers **431** would correspondingly be drivers of the other kinds of elements **407***a-d*. The drivers **431** are in turn connected via pins **401**-**403**, **409** through which they receive control signals and power from the MCU **71** and the battery **83** (via the switch **84**) respectively. FIG. **5** also shows the high voltage charger circuit **81***a* charging the pulse capacitor **81***b*, with the pulse capacitor **81***b* in turn supplying the energy to the waveform generator **406**. The charger circuit **81***a* is connected to the MCU **71** by the pin **410** to

receive an enable signal. While the charger circuit **81***a* and the pulse capacitor **81***b* are not shown with reference to FIGS. **3** and **4**, they can be used for charging the waveform generator **406** shown in the embodiments of the FIGS. **3** and **4** in the same way and with the charger circuit **410** being connected to the pin **410** in the same way.

(50) Conventionally, integrating high-powered components such as the pulse generation circuit **88** described with reference to FIGS. **3**-**5** into an AED requires consideration of dielectric spacing to prevent conducting between components that are not intended to interact with each other. Thus, significant spacing has to be provided between the high-powered components and other components of the AED, thereby increasing the AED size. This challenge can be addressed by including the pulse generation circuit **88** described above with reference to FIGS. **3**-**5** (as well as optionally other components of the AED) in a self-contained module that includes connections to power, control signals, and electrodes **85***a*, **85***b* connected to a patient receiving defibrillation therapy and that is potted inside with an insulating material. FIG. **6** is a perspective view of an isolated module **430** that includes the pulse generation circuit **88** for use in the AED of FIG. **2** in accordance to one embodiment. The pulse generation circuit **88** of any of the embodiments of the FIGS. **3**-**5** is at least partially enclosed within the module **430** that is filled with an insulating material that enhances dielectric properties. Any parts of the circuit **88** that are not within the module **430** can be similarly covered with the insulating material. The insulating material can be epoxy, acrylic, cured silicone, silicone coating, parylene, or another insulating material, and can be applied to the printed circuit board within the module such as through using vacuum, spray or pouring although other techniques are also possible. Underneath the insulating material, the circuit board additionally can be coated with a dielectric insulating material such as parylene, acrylic, silicone or another insulating coating. Once the insulating material has been applied, the conventional spacing rules can be reduced as undesired electrical interactions between the components on the module **430** or the components on the module **430** and other parts of the AED is inhibited by the improved dielectric properties of the insulating materials. The module **430** further includes electrical connections **432** that will interface to the patient through the electrodes **85***a*, **85***b*, and electrical connections to pulse capacitor **81***b*. Auxiliary connections (**436**) connect the module **430** to the battery and the MCU **71**.

(51) Due to the applied insulating material, other components can also be positioned on or near the module **430**. The insulating material shown with reference to FIGS. **7** and **8** is opaque (though other kinds of insulating materials are possible), thus allowing visibility into the components of the module **430** covered by the insulating material. FIG. **7** is a view of a top surface of the module of FIG. **6** in accordance with one embodiment. As seen with reference to FIG. **7**, the solid-state defibrillation waveform therapy generator **406** can be located near the top internal surface of the module **430**, thus being still inside the module **430** and being potted within the insulating material. The opposite internal side of the module can house additional components, such as components for at least one of vital sign monitoring, actigraphy, and motion or environmental information sensing, though other kinds of components are also possible. FIG. **8** is a bottom of the module **430** of FIG. **6** in accordance with one embodiment. The bottom surface of the module **430** (which is still inside the module **430**) can include multiple components that are covered with the insulating material, such as one or more analog-to-digital converters (ADCs) **433**, drivers and bias generating components **434** described above, an ECG frontend **435**, as well other components, such as an actigraphy sensor, thoracic impedance sensor, environmental and motion sensors, and other vital signals and environmental sensing components. Further, this side of the module can include a control interface **436** interfaced to other components of the AED through the contacts.

(52) As can be seen with reference to FIGS. **6**-**8**, in addition, to relaxing requirements for dielectric spacing between components of the AED, the use of the isolated module **430** allows to stack the components vertically (thus decreasing spacing requirements), and also simplifying the manufacturing process for an AED including such a module **430**.

(53) The defibrillation circuit provides a defibrillation waveform or “pulse.” In a further embodiment, pulse generation circuit **88** of the embodiments of FIGS. **3**-**5** can further include a polarity reversal correction circuit to ensure proper shock delivery in the event that the electrode pads **85***a*-*b* are improperly reversed. As further described, depending on the success of the delivery of the shock, polarity could automatically be reversed on the third defibrillation shock, as reversing polarity can aid in defibrillation of difficult cases. In addition to providing control of the waveform, the MCU **71** can further monitor the defibrillation waveform through the sensing circuit **87** and adjust the control and waveform based on the monitoring.

(54) A disposable pocketable AED using the pulse generation circuit **88** is intended to be available at all times and easy to use with little to no training required. FIG. **9** is a flow chart showing a method **170** for operating a disposable pocketable AED in accordance with one embodiment. To start, the AED is activated (step **171**) by the user pressing the “On” switch, removing the outer wrapping, opening the case or similar control, after which the AED executes a power-on self-test (POST) (step **172**).

(55) Following successful POST (step **172**), both a record of the AED's activation is made in an onboard log (step **173**) and the pulse capacitor **81***b* may be optionally pre-charged to a conservative level (step **174**) by the high-

voltage charging circuit **81***a*. The state of the electrode pads is determined (step **175**). If the pads are not correctly applied (step **175**), such as because the user of the AED has removed the pads from the victim **18**, any energy generated for delivery of the shock is dissipated as described above, such as by activating the waveform generator **406** in the transconductance range under the control of the MCU **71** (step **176**), which either ends the method **170** or returns the method to step **175**, depending on the actions of the user.

(56) If the pads are correctly applied, the AED determines whether a shockable rhythm is present (step **177**). Provided a shockable rhythm is sensed (step **177**), the AED issues a warning to the user (step **178**) and a defibrillation shock is delivered (step **179**). The defibrillation shock is delivered as a high voltage therapeutic waveform **180**, preferably as a biphasic waveform, such as a biphasic truncated exponential (BTE), pulsed biphasic, and rectilinear biphasic waveform, modified biphasic, arbitrary or, alternatively, as a monophasic waveform. Other defibrillation waveforms are possible. Once the shock has been delivered, the device determines whether a normal rhythm has been restored and, if so, the methodology is done (step **181**) and the AED will discharge the pulse capacitor **81***b* and power down (step after 15 minutes of a non-VF rhythm (**182**), ending the method **170**. In some cases, several defibrillation shocks are required and the AED delivers biphasic defibrillation shocks, where the initial energy level for defibrillation begins at 120 J and either repeats or escalates for the second and subsequent defibrillation shocks up to a maximum of 360 J. In the use of escalation, the defibrillation energy is automatically adjusted by the AED with each subsequent defibrillation shock. In a further embodiment, based on the findings of a detection algorithm performed by the MCU **71** revealing success or failure of preceding defibrillation shocks the polarity of the defibrillation shock is reversed on the third shock (or any subsequent shock following the first shock) should no restoration of a non-shockable rhythm occur. In a further embodiment, the AED can automatically limit the number of shock re-attempts permitted, as after three defibrillation shocks, resuscitation of the victim **18** becomes unlikely.

(57) In a further embodiment, as part of the process of delivering the defibrillation shock (step **179**), the AED measures patient impedance during application of the defibrillation shock through the sensing circuit and adjusts one or more of the energy, voltage, and pulse width of the defibrillation waveform **180** in real time to generate optimal defibrillation therapy, where the x-axis represents time (T) and the y-axis represents voltage (V). Knowledge of patient impedance is crucial in a traditional design, which is used to determine the energy required to pre-charge the high-voltage pulse capacitor **81***b* to an appropriate level and to aid in realizing an appropriate energy deliver waveform. In practice, patient impedance changes during the shock, so conventional impedance-based pre-charge circuits have limited usefulness in achieving effective defibrillation. For instance, the impedance of a ten-year-old child is around 20 Ohms, whereas a 200-pound, middle-aged male has an impedance of about 75 Ohms. For both individuals, a waveform of 10 msec is likely necessary for effective defibrillation but their defibrillation energy and pre-charge parameters are significantly different. Moreover, impedance on the skin's surface typically decreases as defibrillation therapy progresses. Optionally the MCU **71** (shown in FIG. **2**) interfaces to the sensing circuit to continually measure impedance in real time and adjusts parameters in the high voltage energy delivery module **79**, voltage and pulse width (duration). Other parameters are possible.

(58) For instance, an exemplary biphasic waveform is defined with an asymmetrical 65% tilt from a leading-edge voltage VL and trailing edge voltage VT/−VT with a polarity reversal halfway through the waveform. Patient impedance can affect the duration of the waveform where increased impedance means longer pulse width, lower voltage, or less energy to the heart, and decreased impedance means shorter pulse width, higher voltage, or more energy to the heart (unless patient impedance changes after the impedance is sensed). The most efficacious way to ensure correct energy delivery is to monitor and adjust the therapy in real time. One or more of these parameters can be adjusted by the MCU in real time to alter the amount of primary of the shock to reflect the ideal target therapy represented by the biphasic waveform.

(59) FIG. **10** is a front view showing a disposable single use pocketable AED with dual free-floating electrodes in accordance with one embodiment. The AED **230** combines a highly portable form factor with the charging circuit **88** that deliver defibrillating energy out of only modest lightweight battery capacity. Such a pocket-sized AED can be made readily available not just in the home, but anytime and anywhere that a would-be rescuer happens to be. The AED **230** advantageously uses the charging circuit **88**, as discussed supra with reference to FIG. **3** et seq., to generate the bias voltage driving the waveform generator **406**. This innovation allows the circuit to be powered with a low cost and lightweight battery and the high voltage charger circuit **81***a* and pulse capacitor **81***b* to be down-rated from the high capacitance levels utilized in conventional designs, all of which significantly decreases cost and size, thereby making single-use and device disposability possible.

(60) The AED **230** is housed in a small lightweight housing **231**, about the size and weight of a mobile telephone, that is, in the range of 2.25 to 3.5 inches wide, 5.25 to 7 inches tall, and 0.25 to 1.0 inches deep and a weight in the range of 130 to 550 grams. Other sizes and form factors are possible. The pair of free-floating electrodes **232***a-b* are connected to the housing **231** by a pair of flexible leads **233***a-b*. The charging circuit **88** as described above is

interfaced to the electrodes **232***a, b*. Each electrode **232***a-b* is coated with an adhesive hydrogel that ensures proper contact with the victim's skin. The electrodes **232***a-b* are for a single-use only. The front of the AED **230** has a user interface **234** designed to optimize user understanding that includes a set of visual instructions **237**. Optionally, the AED **230** can be equipped with a speaker (not shown) to generate voice prompts.

(61) The AED **230** includes a streamlined and simple user interface that facilitates understanding and proper use during an emergency by lay people. Power is controlled by a simple “On” switch **235** and the status of the AED **230** is intuitively provided by a visual indicator **236** that changes color depending upon the state of the AED, for instance, through a display of “red,” “yellow” and “green” to respectively indicate device activated but not attached to the patient, device attached and pulse capacitor **81***b* charging, and a ready-to-shock condition. Other colors, forms and types of indicators are possible. Other information, such as impedance and voltage, vital signs, thoracic activity, actigraphy, motion or environmental information, as well as other information can similarly be provided to the user interface or recorded for later analysis. In a further embodiment, the AED **230** includes mobile communications capabilities by which to automatically summon medical assistance, generally by calling 9-1-1 or the equivalent in most localities, upon the sensing of a shockable rhythm. The mobile communications capabilities integrated into the AED **230** by including appropriate circuits and components or through a special features module providing the mobile communications capabilities to the AED. The AED could also receive mobile communications capabilities through a wireless interface, such as WiFi or Bluetooth, over which the AED can communicate to a mobile phone or wide area network, such as the Internet, and relay a 9-1-1 call. Alternatively, a mobile phone or device could be supplemented with the features of the AED **230**.

(62) FIG. **11** is a cut-away view showing block component groups contained within the disposable single use pocketable AED **230** of FIG. **10**. The AED's circuit is provided on a printed circuit board (PCB) **240** contained within the housing **231**, which also contains a low-cost, high-energy density battery **238** (optionally, a primary cell) and a pulse capacitor **239**.

(63) FIG. **12** is a side view showing the disposable single use pocketable AED **230** of FIG. **10** with the housing and dual free-floating electrodes stowed in a carrying case **242**. The AED **230** is intended to be easily carried in a pocket and could be carried in a purse, backpack, glovebox, golf bags, and so forth, so as to enable the AED **230** to be conveniently on-hand in case of an SCA situation in the same manner that most people have their mobile phone on-hand.

(64) FIG. **13** is a side view showing the disposable single use pocketable AED **230** of FIG. **10** with the housing and dual free-floating electrodes partially deployed from the carrying case **242**. The pair of free-floating electrodes **232***a-b* share a similar front profile with the housing **231**. The housing **231** and electrodes **232***a-b* slide out of the carrying case **242** when being deployed.

(65) FIG. **14** is a back view showing the cable management system **241** of the disposable single use pocketable AED **230** of FIG. **10**. A cable management system **241** is used to store the leads **232***a-b* inside of the housing **231**, where the leads are internally retracted by the smart cable management system **241** until needed.

(66) One of the dual free-floating leads **232***a-b* can be eliminated by providing an electrode pad surface on the AED's housing. FIG. **15** is a front view showing a disposable single use pocketable AED **250** with a single free-floating electrode **252** in accordance with one embodiment. As before, the AED **250** is housed in a small lightweight housing **251**, but only one free-floating electrode **252** is connected to the housing **31** by a single flexible lead **253**.

(67) FIG. **16** is a rear view showing the integrated electrode **258** of the disposable single use pocketable AED **250** of FIG. **15**. An integrated electrode pad **258** is provided on a rear-facing surface of the housing **251**. A planar laminated high energy pulse transformer is incorporated into each electrode **252**, **258**, as further discussed infra with reference to FIG. **19**. Both the single free-floating electrode **252** and integrated electrode **258** are coated with an adhesive conductive hydrogel that ensures proper contact with the victim's skin. The front of the AED **250** similarly has a user interface **254** designed to optimize user understanding that includes a set of visual instructions **257**. Optionally, the AED **250** can be equipped with a speaker (not shown) to generate voice prompts. Power is again controlled by an “On” switch or optionally an activation circuit **255** and the status of the AED **250** is provided by a visual indicator **256**. The AED's circuit is provided on a PCB (not shown) contained within the housing **251**, which also contains a low-cost, high-energy density battery (not shown) and pulse capacitor (not shown).

(68) FIG. **17** is a side view showing the disposable single use pocketable AED **250** of FIG. **10** with the housing **251** and single free-floating electrode **252** stowed in a carrying case. The single free-floating electrode **252** shares a similar profile with the housing **251**.

(69) FIG. **18** is a side view showing the disposable single use pocketable AED of FIG. **10** with the housing and single free-floating electrodes partially deployed from the carrying case. The housing **251** and electrode **252** slide out of the carrying case **260** when being deployed. A smart cable management system (not shown) is also used to

store the single lead **253** inside of the housing **251**, where the lead is internally retracted by a cable management system until needed.
(70) FIG. **19** is a top view diagram showing an electrode pad assembly **271** for use in the disposable single use pocketable AEDs **230**, **250** of FIGS. **10** and **15**. Each electrode contains an embedded planar laminated high energy pulse transformer. This type of transformer exhibits high power density by functioning at high switching frequencies, while packaged in a low profile with larger surface area, thereby preventing overheating. In each electrode assembly **271**, a primary winding **272** and a secondary winding **273** are laminated together into a planar transformer **270** with a jumper that is soldered, welded, crimped, or otherwise electrically conducted together.
(71) The circuits described herein provides the basis for external defibrillators that are easy to carry, low cost and lightweight, while delivering a high-voltage, high-energy biphasic shock suitable for cardiac defibrillation and victim resuscitation. External defibrillators utilizing this circuit can help to facilitate the widespread adoption of the portable defibrillation technology and thereby meaningfully help to decrease the number of deaths from sudden cardiac arrest. Moreover, such circuits could also aid in reducing size and cost of implantable defibrillators.
(72) In a further embodiment, the circuits described herein, including the circuits described with reference to FIGS. **3-5**, could be incorporated into an implantable cardioverter defibrillator (ICD). In a still further embodiment, the circuits could be incorporated into a wearable external defibrillator.
(73) The descriptions of the AED and circuits above can be combined with the features described in the following commonly-owned patent documents: U.S. Pat. No. 11,794,026, issued Oct. 24, 2023; U.S. patent application Ser. No. 18/401,199, filed Dec. 29, 2023; U.S. patent application Ser. No. 18/486,992, filed Oct. 13, 2023; and U.S. Patent Application entitled “Solid State Defibrillation Therapy Generator,” Ser. No. 18/806,524, filed Aug. 15, 2024. The entire disclosures of all of these four patent documents is hereby incorporated by reference. While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope of the invention.

Claims

1. A circuit for defibrillation waveform generation, comprising: a bias generation circuit, comprising: a switching regulator in buck configuration, wherein switched output of the regulator is connected to an input of a primary winding of a transformer and wherein an output of the primary winding of the transformer is utilized to supply a regulated DC voltage which powers a microcontroller that is in control of a solid-state therapeutic defibrillation waveform generator; and one or more secondary windings of the transformer whose energy is rectified, wherein the rectified energy is used to supply one or more bias voltages to the solid-state therapeutic defibrillation waveform generator that is used to create a therapeutic defibrillation waveform.
2. A circuit according to claim 1 wherein the solid-state therapeutic defibrillation waveform generator is comprised of one or more of field-effect transistors (FETs), Silicon Carbide FETs, insulated-gate bipolar transistors (IGBTs), silicon controlled rectifiers (SCRs), triode for alternating current (TRIAC), and bipolar junction transistors (BJTs).
3. A circuit according to claim 1, wherein the microcontroller is configured to reverse the polarity of the therapeutic defibrillation waveform by driving the solid-state therapeutic defibrillation waveform generator in a reverse polarity configuration.
4. A circuit according to claim 1, wherein the microcontroller is configured to analyze a result of previous therapeutic defibrillation shocks applied to a patient and is configured to reverse the defibrillation waveform polarity based on a result of the analysis.
5. A circuit according to claim 1, wherein the switching regulator comprises one of a switching controller and an external field-effect transistor (FET).
6. A circuit according to claim 1, further comprising a diode configured to rectify power provided by at least one of the secondary windings.
7. A circuit according to claim 1, further comprising a bridge rectifier configured to rectify power provided by one of the secondary windings.
8. A circuit according to claim 1, further comprising a synchronous rectifier configured to rectify power provided by one of the secondary windings.
9. A circuit according to claim 1, further comprising a free-wheeling diode used across a primary side of the transformer.
10. A circuit according to claim 1, further comprising a synchronous rectifier used across the primary side of the transformer.

11. A defibrillator utilizing a therapeutic defibrillation waveform generation circuit, comprising: a bias generation circuit comprising: a switching regulator in buck configuration, wherein switched output of the regulator is connected to an input of a primary winding input of a transformer, wherein an output of the primary winding of the transformer is utilized to supply a regulated DC voltage to a microcontroller that is in control of a solid-state therapeutic defibrillation waveform generator; one or more secondary windings of the transformer whose energy is rectified; and the rectified energy is used to supply one or more bias voltages; and the solid-state therapeutic defibrillation waveform generator that is configured to create a therapeutic defibrillation waveform utilizing one or more of the bias voltages.
12. A defibrillator according to claim 11, wherein one or more of the bias voltages are regulated down to operate one or more sections of the solid-state defibrillation waveform generator in a transconductance region.
13. A defibrillator according to claim 11 wherein a microcontroller configures the defibrillation waveform generator to shunt an input.
14. A defibrillator according to claim 11, wherein the solid-state defibrillation waveform generator is comprised of one or more of field-effect transistors (FETs), Silicon Carbide FETs, insulated-gate bipolar transistors (IGBTs), silicon controlled rectifiers (SCRs), and bipolar junction transistors (BJTs).
15. A defibrillator according to claim 11, wherein the microcontroller is configured to reverse the polarity of the therapeutic defibrillation waveform by driving the solid-state defibrillation waveform generator in a reverse polarity configuration.
16. A defibrillator according to claim 11, wherein the switching regulator comprises one or more of a switching controller and an external field-effect transistor (FET).
17. A defibrillator according to claim 11, further comprising a diode configured to rectify power provided by the secondary windings.
18. A defibrillator according to claim 11, further comprising one or more of a bridge rectifier and a synchronous rectifier configured to rectify power provided by the secondary windings.
19. A defibrillator according to claim 11, wherein the defibrillator is one of an automated external defibrillator, a wearable external defibrillator, and an implantable cardioverter defibrillator.