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EP-A1- 2 172 245

US-A1- 2006 229 679

VESSELA KRASTEVA ET AL: "Shock Advisory System for Heart Rhythm Analysis During Cardiopulmonary Resuscitation Using a Single ECG Input of Automated External Defibrillators", ANNALS OF BIOMEDICAL ENGINEERING, KLUWER ACADEMIC PUBLISHERS-PLENUM PUBLISHERS, NE, vol. 38, no. 4, 13 January 2010 (2010-01-13), pages 1326-1336, XP019786018, ISSN: 1573-9686

FADDY ET AL: "Reconfirmation algorithms should be the standard of care in automated external defibrillators", RESUSCITATION, ELSEVIER, IE, vol. 68, no. 3, 1 March 2006 (2006-03-01), pages 409-415, XP027919778, ISSN: 0300-9572 [retrieved on 2006-03-01]

WIK L: "Pro cardiopulmonary resuscitation before defibrillation; Für eine kardiopulmonale Reanimation vor Defibrillation", NOTFALL & RETTUNGSMEDIZIN; GERMAN INTERDISCIPLINARY JOURNALOF EMERGENCY MEDICINE, SPRINGER, BERLIN, DE, vol. 15, no. 6, 8 August 2012 (2012-08-08), pages 486-493, XP035121880, ISSN: 1436-0578, DOI: 10.1007/S10049-011-1567-0

lers.

## Description

[0001] The present invention relates to improved apparatus involving the integrated use of Automated External Defibrillators (AEDs) and cardiopulmonary resuscitation (CPR). Specifically, this invention relates to AEDs and methods that quickly and reliably determine the presence of a shockable cardiac rhythm in a cardiac arrest victim during a resuscitation attempt such that minimal delay between CPR and delivery of a defibrillation shock is made possible.

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[0002] Cardiac arrest is widely-understood to be a substantial public health problem and a leading cause of death in most areas of the world. Each year in the U.S. and Canada, approximately 350,000 people suffer a cardiac arrest and receive attempted resuscitation. Accordingly, the medical community has long sought ways to more successfully treat cardiac arrest victims through CPR and application of defibrillation shocks to rapidly restore a normal heart rhythm to persons experiencing this type of event. AEDs were first developed decades ago to help treat incidents of cardiac arrest. Since their creation, AEDs have become prevalent in public locales such as offices, shopping centers, stadiums, and other areas of high pedestrian traffic. AEDs empower citizens to provide medical help during cardiac emergencies in public places where help was previously unavailable in the crucial early stages of a cardiac event.

**[0003]** Fully automated external defibrillators capable of accurately detecting ventricular arrhythmia and nonshockable supraventricular arrhythmia, such as those described in US 5474574, have been developed to treat unattended patients. These devices treat victims suffering from ventricular arrhythmias and have high sensitivity and specificity in detecting shockable arrhythmias in realtime. Further, AEDs have been developed to serve as diagnostic monitoring devices that can automatically provide therapy in hospital settings, as exhibited in US 6658290.

[0004] EP 2172245 A1 shows an external defibrillator comprising an ECG sensing circuit and detection elements that are adapted to obtain an ECG signal corresponding to patient heart activity; and a processor that performs two rhythm analysis algorithms that each evaluate the ECG signal and independently determine a presence of a shockable cardiac rhythm.

[0005] Vessela Krasteva et al., "Shock Advisory System for Heart Rhythm Analysis During Cardiopulmonary Resuscitation Using a Single ECG Input of Automated External Defibrillators", Annals of Biomedical Engineering, Kluwer Academic Publishers-Plenum Publishers, NE, Vol. 38, no. 4, 13 January 2010 (2010-01-13), pages 1326-1336, XP019786018, ISSN 1573-9686, acknowledge to necessity to minimize "hand-offs" intervals during CPR. They present a shock advisory system for a fully automated defibrillation during CPR.

**[0006]** Faddy et al., "Reconfirmation algorithms should be the standard of care in automated external defibrilla-

tors", Resuscitation, Elsevier, IE, Vol. 68, no. 3, 1 March 2006 (2006-03-01), pages 409-415, XP027919778, ISSN 0300-9572, disclose the use of reconfirmation algorithms in AEDs to verify any shockable rhythm changes to a non-shockable rhythm. Said algorithms operate from the time of decision to shock until the shock is delivered. In the AED a first algorithm is used to analyze physiological information such as ECG data. A decision to initiate a shock is re-evaluated by a second algorithm.

[0007] US 2006/229679 relates to AEDs. [0008] Despite advances in AED technology, many current AEDs are not fully functional in implementing the current medically suggested methods of integrated CPR and AED use. Most of the AEDs available today attempt to classify ventricular rhythms and distinguish between shockable ventricular rhythms and all other rhythms that are non-shockable. This detection and analysis of ventricular rhythms provides some real-time analysis of ECG waveforms. However, the functionality, accuracy and speed of a particular AED heavily depends on the algorithms and hardware utilized for analysis of ECG waveforms. In many implementations, the algorithms used in AEDs depend on heart rate calculations and a variety of morphology features derived from ECG waveforms, like ECG waveform factor and irregularity as disclosed in US 5474574 and US 6480734. Further, in order to provide sufficient processing capability, current AEDs commonly embed the algorithms and control logic into microcontrol-

30 [0009] As advances have taken place in the field of AEDs, there have been significant medical advancements in the understanding of human physiology and how it relates to medical care as well. These advancements in medical research have lead to the development
 35 of new protocols and standard operating procedures in dealing with incidents of physical trauma. For example, in public access protocols for defibrillation, recent guidelines have emphasized the need for the use of both CPR and AEDs and suggested an inclusive approach involving defibrillation integrated with CPR.

**[0010]** Along with its advantages, integrated use of CPR with defibrillation can, however, negatively impact the operation of an AED as chest compressions and relaxations are known to introduce significant motion artifacts in an ECG recording. During and after CPR, where a rescuer is instructed to apply chest compressions and relaxations at a prescribed rate of approximately 100 cycles per minute, the ability to obtain clean signal data from the patient can be challenging.

[0011] In addition to the difficulty of obtaining a clean ECG signal, the importance of doing this quickly has recently been highlighted as the current AHA Guidelines emphasize the importance of minimizing interruptions between CPR and defibrillation. The guidelines state, "[d] efibrillation outcome is improved if interruptions (for rhythm assessment, defibrillation, or advanced care) in chest compressions are kept to a minimum", and "[m] inimizing the interval between stopping chest compres-

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sions and delivering a shock (ie, minimizing the preshock

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pause) improves the chances of shock success and patient survival." See Circulation 2010, 122: S678, S641. [0012] Some past AEDs implement an algorithm that requires an extended period of clean ECG signal data during a rescue to classify a sensed ventricular rhythm as shockable. Some prior art disclosures requiring a clean signal also discuss carrying out an initial assessment of ECG when CPR is ongoing, before relying on a temporary stoppage in CPR to acquire and perform an ECG analysis. Moreover, much of the recent scholarship in this area involves using tools which enable the entire analysis of ECG to take place while CPR is ongoing such that little or no stoppage of CPR is required. Accordingly, numerous techniques for identifying and filtering CPR artifacts for the purpose of ECG signal analysis have been proposed. However, many of these methods and analysis techniques have limitations or raise concerns related to providing appropriate care, especially in view of the newest AHA guidelines.

**[0013]** Accordingly, improved methods and apparatus for quickly assessing shockable cardiac rhythms which minimize any time periods between CPR and delivery of a defibrillation shock by an AED are desired.

[0014] The invention is defined by claim 1.

**[0015]** Various embodiments of the present invention can overcome the problems of the prior art by providing a method and device to rapidly, but accurately, determine and verify the presence of a shockable cardiac rhythm to minimize delay between CPR and delivery of a defibrillation shock by a rescuer.

[0016] In one embodiment, an automated external defibrillator (AED) is provided. This AED includes an ECG sensor that obtains an ECG signal corresponding to patient heart activity and a prompting device that provides cardiopulmonary resuscitation (CPR) instructions. Further, the AED also has a control system including a microprocessor programmed to run two rhythm analysis algorithms after instructions to terminate CPR have been provided. The two rhythm analysis algorithms analyze segments of the ECG signal for recognizing the presence of a shockable rhythm. One of the two rhythm analysis algorithms provides a delayed start shockable rhythm verification algorithm. The AED additionally includes a therapy generation circuit for treating the shockable rhythm with a defibrillation pulse in response to the control system determining the presence of a shockable rhythm.

[0017] In another embodiment according to the present invention, an AED is disclosed. The AED includes an ECG sensor that obtains an ECG signal corresponding to patient heart activity. The AED also includes a prompting device for providing CPR instructions. The AED further includes a control system including a microprocessor in which the control system is adapted to determine the presence of a shockable a cardiac rhythm in a first segment of the ECG signal using a first algorithm. The control system is further adapted to de-

termine the presence of a shockable cardiac rhythm in a second segment of the ECG signal using a second verification algorithm. The first algorithm and second verification algorithms run in parallel and analyze segments of the ECG signal. In this embodiment, the first segment begins when instructions to cease CPR are given. Thereafter, the second segment begins after a short number of seconds. The AED of this embodiment further includes a power generation circuit for providing power for a defibrillation pulse that may be used to treat shockable rhythms and a pulse delivery circuit.

[0018] According to an embodiment of the present invention, an automated external defibrillator is provided for reducing the delay between termination of cardiopulmonary resuscitation and administration of a defibrillating shock. The AED includes an ECG sensor that obtains an ECG signal corresponding to patient heart activity and a processor. The processor runs multiple rhythm analysis algorithms that each independently determine the presence of a shockable rhythm based segments of the ECG signal with different start times following cardiopulmonary resuscitation in order to verify the presence of a shockable rhythm.

[0019] An operating method for an automated external defibrillator (AED) for delivering a defibrillation shock includes charging an AED during cardiopulmonary resuscitation (CPR), prompting a break in CPR with a prompting device of the AED, and analyzing a first segment of patient ECG data immediately following CPR with a first algorithm to determine if the ECG data has an initial shockable classification. The method also includes monitoring the ECG data with the first algorithm after the initial shockable classification to verify that the shockable classification remains consistent. The method further includes analyzing a second segment of the ECG data with a delayed start time compared to the first segment of ECG data with a second verification algorithm while the first algorithm is concurrently analyzing and monitoring ECG data to obtain an independent rhythm classification. The method also includes the step of comparing using the rhythm classification of the second algorithm with the classification of the first algorithm to provide resuscitation advice

[0020] Yet another operating method for an AED for reducing the delay between termination of cardiopulmonary resuscitation and administration of a defibrillating shock with the AED includes the steps of prompting to initiate CPR, charging the AED, and prompting a break in CPR, analyzing a first set of ECG data immediately following CPR with a first algorithm to determine if the ECG data has a shockable rhythm classification. The method also includes the steps of analyzing a second set of ECG data obtained with a delayed start with respect to the first set of ECG data to determine if the ECG data has a shockable rhythm classification, and comparing the classification of the first set of ECG data and the second set of ECG data to determine whether a defibrillation shock should be delivered by the AED.

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**[0021]** The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

- FIG. 1 illustrates generally an example of a cardiac arrest victim being treated with CPR and an AED,
- FIG. 2 illustrates generally an example of a schematic drawing of the hardware of an AED,
- FIG. 3 illustrates generally a flowchart of the operation steps of the AED rhythm analysis, FIG. 4 illustrates generally a chart setting forth an example timeline of rhythm assessment and AED operation with a successful match of rhythm assessment in algorithms generally run in parallel, and
- FIG. 5 illustrates generally a chart setting forth an example timeline of rhythm assessment and AED operation which does not include a successful match of rhythm assessment in generally parallel algorithms.

**[0022]** The invention may be embodied in other specific forms without departing from the scope of the claims, therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive.

[0023] In various embodiments of this invention an apparatus is disclosed for rapidly and reliably evaluating an ECG signal from a patient such that minimal delay between CPR and delivery of a defibrillation shock is made possible. Fig. 1 depicts a cardiac arrest victim who is undergoing a resuscitation attempt and is being treated with an AED and CPR. The AED 100 is shown with electrode pads 104 and 106 coupled to the patient's chest and the rescuer 108 is shown in position for rapidly providing chest compressions to the patient 110.

[0024] The American Heart Association currently recommends that all rescuers, regardless of training, should provide chest compressions to all cardiac arrest victims, and that chest compressions should be the initial CPR action for all victims regardless of age. CPR typically improves a victim's chance of survival by providing critical blood circulation in the heart and brain. It will be understood that CPR includes both chest compression and lung inflation, where oxygen is provided to the lungs either by mouth-to-mouth inflation or as a result of movement of the lungs due to the chest compression only.

[0025] Often, CPR alone will be insufficient to reverse cardiac arrest in a patient. In these cases, an AED 100 may be used to deliver an impulse of high amplitude current to a patient's heart to restore it to normal cardiac rhythm. However, there are many different types of heart rhythms, only some of which are considered shockable. The primary shockable rhythms are ventricular fibrillation (VF), ventricular tachycardia (VT), and ventricular flutter. Non-shockable rhythms may include bradycardias, electro-mechanical dissociation, idio-ventricular rhythms,

and normal heart rhythms.

[0026] In order to determine if a rhythm is shockable, AEDs analyze ECG data to classify the type of rhythm the patient is experiencing. Specifically, a pair of AED electrodes 104 and 106 are positioned on the patient's chest, as shown in Fig. 1, to obtain an ECG signal. Next, the ECG signal is analyzed by the AED and if the cardiac rhythm is deemed shockable, a defibrillation pulse is delivered to the patient.

[0027] AEDs relying upon such an ECG analysis may be considered semi-automatic or fully-automatic. In general, semiautomatic defibrillators require a user to press a button to deliver the actual defibrillating shock, compared to fully-automatic defibrillators that can deliver therapy without such an input of the user. Various embodiments of the present invention can work with either automatic and/or semi-automatic AEDs.

[0028] In Fig. 1, the AED 100 is shown coupled to a pair of electrodes 104 and 106 located on the patient's chest 110. The AED 100 is equipped with a central compartment having a hinged lid 112 to house the electrode pads 104 and 106 when the defibrillator is not in use. The lid 112 is shown in an open configuration in Fig. 1 and accordingly, is ready for use. In one embodiment, opening this lid 112 activates the AED 100 and begins sending prompts to the user. Prompts may include voice prompts from speaker 114 and visual prompts from the display 116.

[0029] Fig. 2 illustrates generally a block diagram of the hardware of an AED 200 implementing the improved shocking algorithms according to one embodiment of the invention. A digital microprocessor-based control system 202 is used for controlling the overall operation of AED 200. The electrical control system 202 further includes an impedance measuring circuit for testing the interconnection and operability of electrodes 204 and 206. Control system 202 includes a processor 208 interfaced to program memory 210, data memory 212, event memory 214 and real time clock 216. The operating program executed by processor 208 is stored in program memory 210. Electrical power is provided by the battery 218 and is connected to power generation circuit 220.

[0030] Power generation circuit 220 is also connected to power control unit 222, lid switch 224, watch dog timer 226, real time clock 216 and processor 208. A data communication port 228 is coupled to processor 208 for data transfer. In certain embodiments, the data transfer may be performed utilizing a serial port, usb port, firewire, wireless such as 802.11x or 3G, radio and the like. Rescue switch 230, maintenance indicator 232, diagnostic display panel 234, the voice circuit 236 and audible alarm 238 are also connected to processor 208. Voice circuit 236 is connected to speaker 240. In various embodiments, rescue light switch 242 and a visual display 244 is connected to the processor 208 to provide additional operation information.

[0031] In certain embodiments, the AED will have a processor 208 and a co-processor 246. The co-proces-

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sor 246 may be the rhythm analysis algorithm implemented in hardware and operably connected to the processor over a high-speed data bus. In various embodiments, the processor 218 and co-processor 246 are on the same silicon and may be implemented in a multi-core processor. Alternatively, the processor 208 and co-processor may be implemented as part of a multi-processor or even networked processor arrangement. In these embodiments, the processor 208 offloads some of the calculations to the co-processor thus optimizing the processing of the sensed signals from the electrodes 204 and 206. In other embodiments, the processor 208 is optimized with specific instructions or optimizations to execute calculations. Thus, processor 210 may execute calculations in fewer clock cycles and while commanding fewer hardware resources. In other embodiments, the logic and algorithm of the control system 202 may be implemented in logic, either hardware in the form of an ASIC or a combination in the form of an FPGA, or the like. In any case, a processor device is provided which is adapted to perform the rhythm analysis algorithms discussed below.

[0032] High voltage generation circuit 248 is also connected to and controlled by processor 208. High voltage generation circuit 248 may contain semiconductor switches (not shown) and a plurality of capacitors (not shown). In various embodiments, connectors 250, 252 link the high voltage generation circuit 248 to electrodes 204 and 206. Note that the high voltage circuit here is battery powered and is of high power.

[0033] Impedance measuring circuit 254 is connected to both connector 250 and real time clock 216. Impedance measuring circuit 254 is interfaced to real time clock through analog-to-digital (A/D) converter 256. Another impedance measuring circuit 258 may be connected to connector 250 and real time clock 216 and interfaced to processor 208 through analog-to-digital (A/D) converter 256. A CPR device 260 may optionally be connected to the processor 208 and real time clock 216 through connector 252 and A/D converter 256. The CPR device 260 may be a chest compression detection device or a manual, automatic, or semi-automatic mechanical chest compression device. Additional detailed discussions of some AED designs can be found in US 2011/0105930 and US 5474574, 5645571, 5749902, 5792190, 5797969, 5919212, 5999493, 6083246, 6246907, 6263238, 6289243, 6658290, 6993386.

[0034] The methods and systems utilized by embodiments of the present invention generally consist of employing two instances of rhythm analysis algorithms 300 and 301 that operate in parallel for assessment and verification in an AED or similar cardiac resuscitation device (like the one depicted in Fig. 2, for example) so as to improve the time to deliver therapy. The first rhythm analysis algorithm 300 operates immediately, with little or no initial hold-off period from the AED's instruction to cease CPR. The second algorithm is a verification algorithm and default therapy recommendation algorithm. The second rhythm analysis verification algorithm 301 operates

after a delayed start, i. e. after the first rhythm analysis algorithm 300, as a verification algorithm. Specifically, the second rhythm analysis verification algorithm 301 starts operating after a hold-off period that is designed to reduce the impact of CPR artifacts on rhythm analysis. The defibrillator will advise shock if after an initial learning period, the first instance of rhythm analysis 300 indicates the presence of the same shockable rhythm throughout and a rhythm classification from the second rhythm analysis verification algorithm 301 coincides with that of the first classification from the first rhythm analysis algorithm 300. If the rhythm classifications do not match, the second rhythm analysis verification algorithm 301 is allowed to complete a full analysis and monitoring period and the classification resulting from that second algorithm 301 is used to determine the classification as well as any subsequent protocol advice for rescue.

[0035] Fig. 3 sets forth a more detailed flowchart de-

scribing the operational steps of an AED which utilizes a rhythm analysis coordinating two algorithms directed at segments with different start points for analysis of an ECG signal to quickly arrive at a cardiac rhythm classification and to verify assessments of shockable status. [0036] Specifically, operation of the AED 100 with one embodiment of the rhythm analysis algorithm first charges the AED capacitors with the internal battery during CPR, as set forth at numeral 302. This charge may be triggered in a variety of ways. In some embodiments, charging may occur simply by activating the AED 100 by opening its cover, turning it on, or other similar method. In other preferred embodiments, charging only will occur if a previous analysis has found a shockable rhythm so that the operating life of the battery is not negatively impacted in a substantial way by such pre-charging. Next, at an appropriate point during CPR, the AED 100 provides a prompt, e.g. a voice prompt, indicating that the user 108 should stop CPR, as represented by numeral 304. Immediately following the prompt either a momentary analysis holdoff period or no holdoff period at all is provided, as represented at 306. Any preliminary analysis holdoff period only lasts for around one second in various embodiments. Next, a first (or primary) rhythm analysis algorithm (RAA) engine (a first rhythm analysis algorithm 300 engine) is started at 308 and is analyzed at 310. An analyze period for this algorithm may last for about four seconds in some embodiments. The first rhythm analysis algorithm 300 follows the analyze period with an operation at 312 in which a shockable decision is reached and monitored for a short length of time. In some embodiments, this shockable decision and monitoring phase lasts for around five seconds. A determination is then made at 314 if a consistent classification of a shockable rhythm has remained throughout the monitoring phase. While the first rhythm analysis algorithm 300 is being carried out, a second rhythm analysis verification algorithm 301 operates simultaneously in a par-

allel evaluation of ECG rhythm data. This second (or sec-

ondary) rhythm analysis verification algorithm 301 begins

with an analysis holdoff period 316 which starts as the first rhythm analysis operation 310 begins. Next, the second rhythm analysis verification algorithm 301 starts when the holdoff period completes at 318. By delaying the start of the second rhythm analysis verification algorithm 301, data artifacts and disturbances that might impact signal integrity or the ability to obtain a clean signal are greatly reduced, but without reliance on any filtering of the ECG signal. The second rhythm analysis algorithm 301 then enters an analyze phase 320. This analyze period 320 may last for five seconds, for example, in some embodiments. At the end of this period, a determination is made at 322 classifying the rhythm as shockable or non-shockable.

[0037] Next, if the rhythm is deemed shockable by the second algorithm 301 and the first algorithm 300 gave a consistent classification indicating a shockable rhythm throughout the monitoring period, a shock is issued, at step 324. In the case that either the first algorithm 300 was not consistently classified as shockable throughout the monitoring period or the second algorithm 301 classification was not shockable, the second algorithm classification is continued at 326.

[0038] The second algorithm is then classified as shockable or non-shockable throughout a continued period of monitoring and analysis at 328. If the classification is shockable, a defibrillation shock is issued at 330. If the rhythm is not classified as shockable, no shock is delivered and further CPR or rescue protocol prompts or recommendations are provided, at 332.

[0039] For purposes of this disclosure, the first rhythm analysis algorithm may also be understood as a primary rhythm analysis algorithm and the second rhythm analysis verification algorithm may also be understood as a secondary rhythm analysis algorithm or a second rhythm analysis algorithm in various embodiments. In certain embodiments, each of the rhythm analysis algorithms can be understood to be modified versions of the RHYTH-Mx® software algorithm of Cardiac Science Corporation. Note that this method may make use of existing rhythm analysis algorithms in current AEDs or be part of completely updated algorithms used to control AED operation in various embodiments.

[0040] Use of two independent rhythm analysis algorithms for a shockable assessment and verification process is a useful and advantageous alternative over past prior art techniques. For example, alternative windowing techniques have been used throughout the prior art which restrict therapy decision-making to assessments of contiguous windows which are further subjected to a voting process to enhance consistency. This windowing technique has been modified somewhat in other disclosures to use overlapping windows of data for speeding up this assessment. One signal analysis technique that models overlapping windows and has been know for decades for doing so is referred to as Welch's method although other similar techniques exist. Welch's method essentially teaches reduction in noise signals, like ECG signals,

using spectral density estimation. The method is based on the concept of using periodogram spectrum estimates which are the result of converting a signal from the time domain to the frequency domain. Basically, a signal is split up into overlapping segments that are windowed and a Fourier transform operation is used to provide an array of power measurements vs. frequency bin. This overlapping in Welch's technique is deemed useful as it reduces problems at the boundaries between windows but provides a different computational methodology for approaching the problem of speeding up a rhythm assessment and specifically dealing with problematic post CPR signals. See US 7463922.

[0041] The current disclosure does not use such a windowing technique, and instead approaches the problem in a different way using a targeted assessment and verification process. It has been found that use of the currently disclosed, non-windowing process, that makes use of two entirely separate algorithms and verification process, allows one to better rapidly assess and verify the shock assessment. The methods discussed in the current application both make use of the period immediately following CPR and yet take into account the potential noise inaccuracies of this period, in a way that windowing data by past techniques does not contemplate. Preferably, both algorithms are identical apart from the one being delayed to the other.

[0042] Fig. 4 depicts the rhythm analysis process in an alternate timeline format. Specifically, Fig. 4 is a chart 400 setting forth an example timeline of rhythm assessment and AED operation with an initial match of rhythm assessment in the generally parallel rhythm analysis algorithm 300 and the rhythm analysis verification algorithm 301. In this example, an ECG signal is analyzed and a defibrillation shock is delivered within ten seconds of CPR.

[0043] The first timeline section 402 represents a ten second period of charging that occurs while CPR is performed. The end of the first timeline segment 402 corresponds to commencement of a prompt, e. g. a voice prompt, of the AED that occurs at 404. This prompt at 404 instructs the rescuer to stop CPR and not to touch the victim. Specifically, the prompt state, "Do Not Touch Patient! Analyzing Heart Rhythm."

[0044] The prompt to cease CPR also coincides with the start of an analysis period 406 by the first rhythm analysis algorithm 300. This analysis period 406 could last for five seconds, as depicted in the chart, or for another suitable alternative time period. The first second of this analysis period 406 can include a brief hold-off period, such as a one second delay in some embodiments as well. During the analysis period 406, ECG data is acquired and analyzed with respect to the shockability of the heart activity data presented. This is followed by an analysis and monitoring period 408. This period 408 begins with an assessment of the cardiac condition of ECG data indicating that either a shockable or non-shockable cardiac rhythm is present. This assessment is then con-

tinued to be analyzed and monitored over the analysis and monitoring period 408 to ensure that a consistent shockable or non-shockable assessment is made throughout this time period.

[0045] Concurrently with the analysis period 406, the second rhythm analysis verification algorithm 301 carries out an initial hold-off period 410. This hold-off period 410 may last four to five seconds in some embodiments, for example. The hold-off period 410 is useful, in that, it avoids signals immediately following CPR and any potential impact of data artifacts and disturbances on signal integrity or on the ability to obtain a clean signal. The hold-off period 410 many culminate in a short learn period 412 in some embodiments in which ECG data is obtained. Once the hold-off period 410 is complete, acquired ECG data is evaluated by the second rhythm analysis verification algorithm 301 during an analyze period 414 to determine if a shockable or non-shockable rhythm exists. After a short time in the analyze period 414 (five seconds in some embodiments) a shockable rhythm determination is made which is compared to the determination made and monitored by the first rhythm analysis algorithm 300 during the concurrent period 408.

[0046] Fig. 4 illustrates an instance in which the classification during the analysis and monitor period 408 is "shockable" and the assessment after the first seconds of the analyze period 414 is also "shockable". Because both of these classifications match, instructions to deliver a shock are immediately provided by the AED control circuit. Such a quick shock decision is accordingly made possible because this method increases confidence in early rhythm classifications that may be determined soon after CPR.

[0047] Fig. 5 is a chart 500 setting forth an example timeline of rhythm assessment and AED operation which does not include an initial match of rhythm assessment in the parallel algorithms. Here, either the period 508 did not maintain a consistent "shockable" classification or the second rhythm analysis verification algorithm 301 revealed a non-shockable cardiac rhythm. In this situation, the rhythm analysis algorithm 301 completes an analysis period 514 and requests therapy based upon the classification determined by rhythm analysis algorithm 301 alone.

[0048] A further set of prompts, e. g. voice prompts, from the AED are depicted in Figs. 4 and 5. These further prompts occur following the instructions given not to touch the patient at 404. Specifically, the subsequent prompts 416 will announce "Preparing Shock. Move Away From The Patient!"

[0049] With respect to battery charging, this charging is designed to continue during a period 418 partially common to the analyze and hold-off periods 406, 408, 410, 412 and 414. However, the battery charge is short enough to be ready for defibrillation pulse delivery before an early shock decision can be made. Fast charging batteries are possible in some embodiments as well, which could complete charging is much less time than depicted

in Figs. 4 and 5.

[0050] It should also be appreciated that the exemplary embodiment or exemplary embodiments are only examples, and are not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the foregoing detailed description will provide those skilled in the art with an enabling disclosure for implementing the exemplary embodiment or exemplary embodiments. It should be understood that various changes can be made in the function and arrangement of elements without departing from the scope of the invention as set forth in the appended claims and the legal equivalents thereof. [0051] The embodiments above are intended to be illustrative and not limiting. Additional embodiments are within the claims. Although the present invention has been described with reference to particular embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

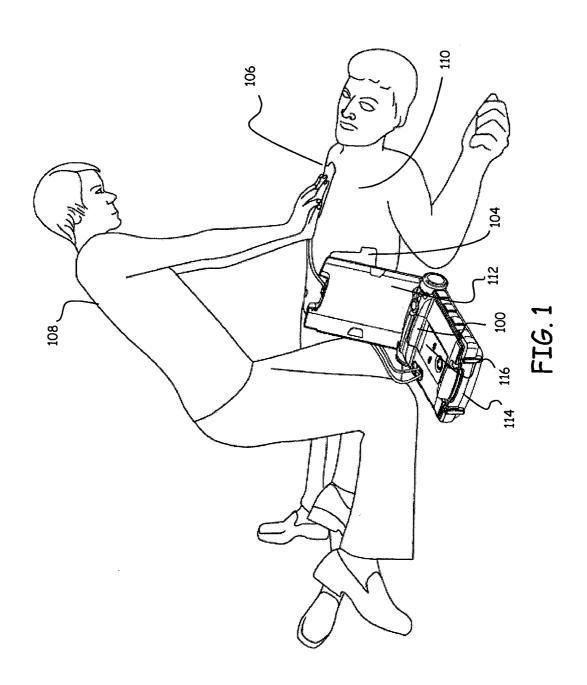
[0052] Various modifications to the invention may be apparent to one of skill in the art upon reading this disclosure. The various features described above should all be regarded as example embodiments, rather than limitations to the scope of the invention, as defined by the claims.

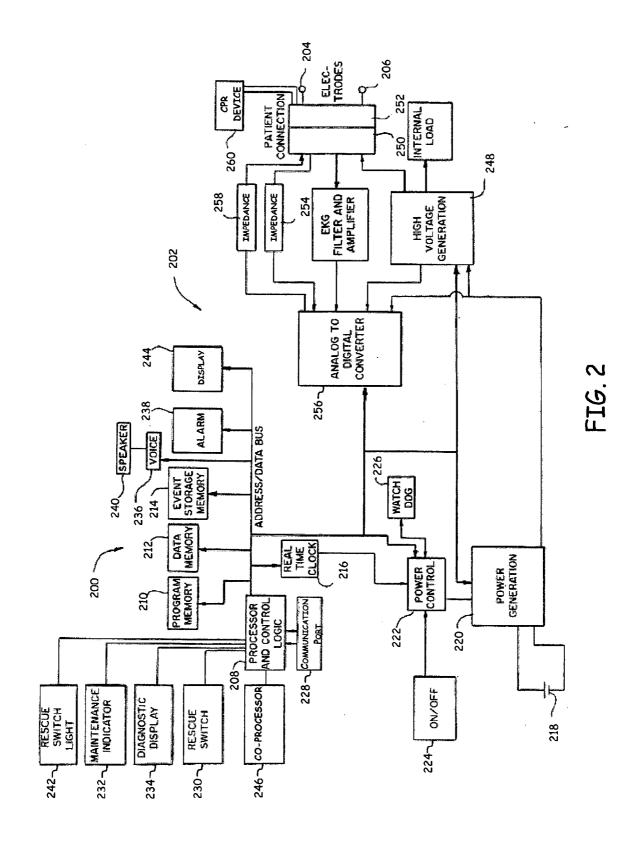
## **PATENTKRAV**

- 1. Ekstern defibrillator omfattende: en EKG føler, som tilvejebringer et EKG signal svarende til patienthjerteaktivitet; og en analyseindretning (202), som er indrettet til at udføre to rytmeanalysealgoritmer (300, 301), som hver især evaluerer EKG signalet og uafhængigt bestemmer en tilstedeværelse af en hjerterytme, som kan stødes, under en analyseperiode, **kendetegnet ved**, **at** de to rytmeanalysealgoritmer har forskellige starttidspunkter, efterfølgende en afslutning af hjertelungegenoplivning (HLG), og at defibrillatoren omfatter en opfordringsindretning (114, 116) og en styreindretning (202), som styrer opfordringsindretningen (114, 116) til at tilvejebringe opfordringsinstruktioner, som instruerer en bruger om at afslutte HLG, samtidigt med starten af analyseperioden (406) for den første rytmeanalysealgoritme (300).
- Defibrillator ifølge krav 1, hvor en første (300) af de to rytmeanalysealgoritmer (300,
  301) omfatter analyse af EKG signalet, som modtages umiddelbart efterfølgende instruktionerne fra opfordringsindretningen (114, 116) om at afslutte HLG.
- Defibrillator ifølge krav 1 eller 2, hvor en anden (301) af rytmeanalysealgoritmerne
  (301) analyserer EKG signalet, som er tilvejebragt efter adskillige sekunders forsin kelse efter instruktionerne fra opfordringsindretningen (114, 116) om at afslutte HLG.
  - 4. Defibrillator ifølge ethvert af de foregående krav, hvor EKG føleren omfatter et par elektroder (104, 106; 204, 206).
- 5. Defibrillator ifølge ethvert af de foregående krav, hvor de to rytmeanalysealgoritmer (300, 301) er i det væsentlige den samme algoritme, og alene afviger med hensyn til deres starttidspunkter.
- 6. Defibrillator ifølge ethvert af de foregående krav, hvor analyseindretningen (202) er indrettet til at bestemme tilstedeværelsen af en hjerterytme, som kan stødes, i et første afsnit af EKG signalet, under anvendelse af den første algoritme (300), og at bestemme tilstedeværelsen af hjerterytmen, som kan stødes, i et andet segment af EKG signalet, under anvendelse af den anden algoritme (301), hvor den første algoritme (300) og den anden algoritme (301) forløber parallelt og analyserer i det mindste nogle fælles segmenter af EKG signalet, og hvor det første segment begynder

efter afslutningen af HLG og det andet segment begynder efter adskillige sekunder efter at det første segment begynder.

- 7. Defibrillator ifølge ethvert af de foregående krav, omfattende et terapigenereringskredsløb (248) til behandling af hjerterytmen, som kan stødes, med en defibrilleringsimpuls, som svar på at analyseindretningen (202) bestemmer tilstedeværelsen af en hjerterytme, som kan stødes.
- Defibrillator ifølge krav 1 og 7, hvor defibrillatoren er konfigureret til at tilvejebringe
  et defibrilleringsstød mindre end 10 sekunder efter instruktionen om at afslutte HLG, i tilfælde hvor tilstedeværelsen af en hjerterytme, som kan stødes, bestemmes.
  - 9. Defibrillator ifølge ethvert af de foregående krav, omfattende en brystkompressionsindretning (260) til at levere HLG.





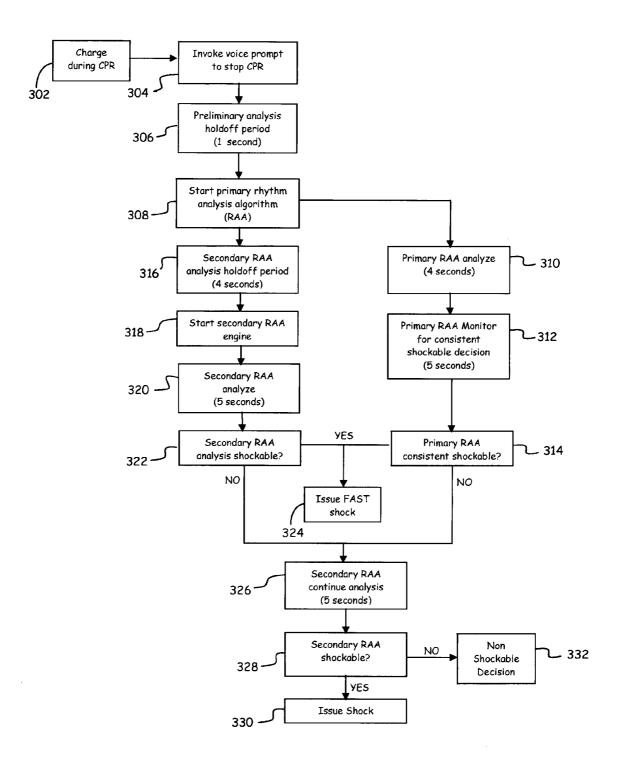
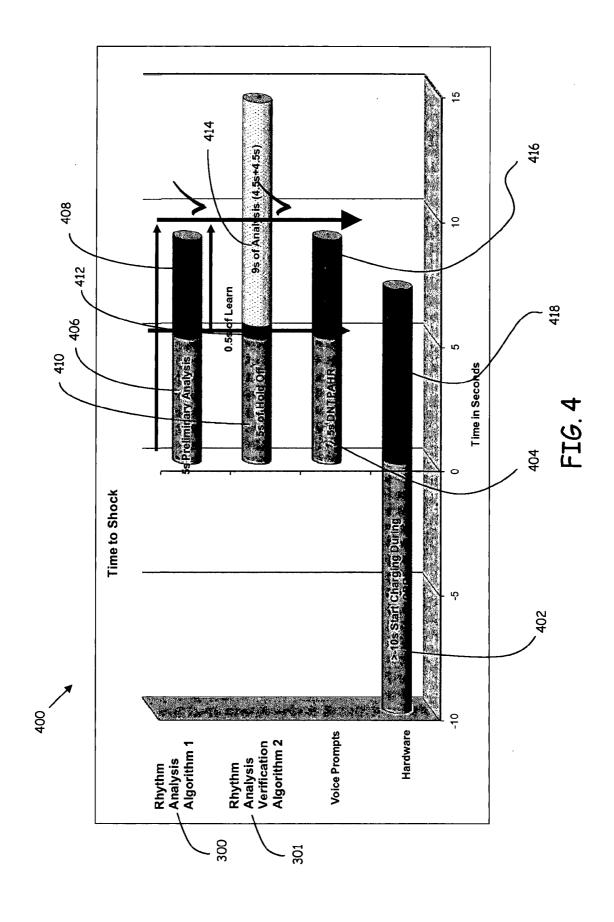


FIG. 3



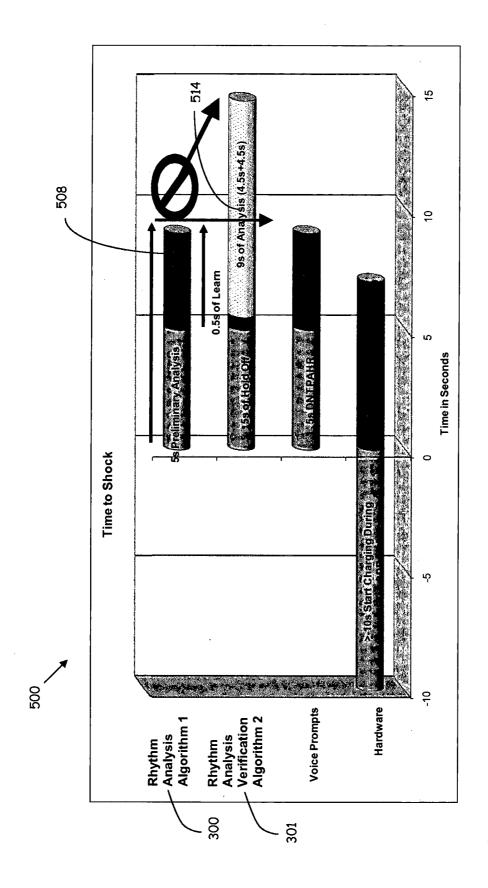


FIG. 5