
(21) International Application Number: PCT/US2004/003999

(22) International Filing Date: 11 February 2004 (11.02.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
   60/448,415 18 February 2003 (18.02.2003) US
   10/652,965 29 August 2003 (29.08.2003) US

(71) Applicant (for all designated States except US):
MEDTRONIC PHYSIO CONTROL CORPORATION [US/US]; 11811 Willows Road NE, P.O. Box 97006, Redmond, WA 98073-9706 (US).

(72) Inventors:

(75) Inventors/Applicants (for US only):

(74) Agents: TAYLOR, Craig, F. et al.; Fredriksson & Byron, P.A., 4000 Pillsbury Center, 200 South Sixth Street, Minneapolis, MN 55402-1425 (US).


(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(54) Title: DEFIBRILLATORS CAPABLE OF ADAPTING TO A CONCURRENT NOT PERFORMED BY THE DEFIBRILLATOR

(57) Abstract: A defibrillating device according to the present invention includes a defibrillator module for defibrillating a person and a data input module coupled to the defibrillator module for making the defibrillator module aware of another therapy or therapies being performed on the person, where the therapies are not being performed by the defibrillating device. The defibrillating device can operate autonomously, yet become aware of other, concurrent and independent therapies being performed on the person. The defibrillating device provided by the invention can then modify the operation of the defibrillating device responsive to the awareness of the other, applied therapy or therapies. Defibrillators can be coupled to sensors, leads, and electrodes for measuring attributes of the person. The defibrillators can generate defibrillation pulses, pacing pulses, and informational output for human consumption. In one embodiment, defibrillation pulses are provided in synchrony with chest compressions measured by sensors coupled to the defibrillator.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
DEFIBRILLATORS LEARNING OF OTHER CONCURRENT THERAPY

BACKGROUND OF THE INVENTION

Field of the invention

The present invention is related to the field of resuscitation devices.

Description of the related art

All over the world, people experience cardiac and respiratory events. For example, both in and out of the hospital, there is a significant incidence of cardiac and/or respiratory arrest. For these situations, a variety of therapies may be appropriate. The patient may require artificial respiration, chest compressions, defibrillation, and/or pacing.

Many devices exist for each of these events and situations. For example, a chest compression device is taught in patent US 6,234,984 B1. Some of these devices even aggregate such features, such as are described in U.S. Patent No. 4,349,015, and U.S. Patent No. 4,424,806.

An external defibrillator is used in an emergency situation of Sudden Cardiac Arrest (SCA). In some instances, a defibrillator may become available where another emergency therapy is already being used. For example, Cardio-Pulmonary Resuscitation (CPR) may be administered, or ventilation, or even cooling to induce mild hypothermia to prevent damage. Not knowing better, an untrained user may feel compelled to discontinue treatment by the other emergency resuscitation device, so that the defibrillator can be used.

Summary of the Invention

Generally, the present invention provides devices, softwares, and methods as described below. An external defibrillator according to the invention inquires whether another emergency resuscitation therapy is being applied concurrently and independently. The defibrillator learns an answer to the inquiry either by analyzing patient inputs that it is detecting, or from direct input by the user, via an interface.

In optional preferred embodiments, the external defibrillator even coordinates its electrotherapy with the other therapy for optimum effect. Coordination is performed either by coordinating the timing of electrotherapy, or by instructing other therapy to be performed or continue to be performed.

The invention offers the advantage that the overall therapy to the patient is optimized, without needing to plan coordination of the devices.
The present invention can provide a defibrillating device including a defibrillator module for defibrillating a person, and at least one human interface module for accepting input from a human operator, in which the human interface module accepts human entered indications of a therapy being performed on the person, where the therapy is not being performed by the defibrillating device. The device can further include a controller coupled to the human interface module for varying operation of the defibrillating device responsive to the human input. The controller may vary operation of the defibrillator module.

In some devices, the human interface module includes a voice input module. The human interface module optionally includes a manual input module to accept manually input data. In some devices, the defibrillating device controller varies defibrillating responsive to the indication of the therapy. In other devices, the defibrillating device controller inhibits generation of a defibrillation pulse responsive to the indication of the therapy.

Some defibrillating devices generate instructions to a human assistant, which can include instructions to administer chest compression on the patient.

In some devices, a respiration sensor, a force sensor, a motion sensor, a displacement sensor, an accelerometer, a temperature sensor, ECG leads, or combinations thereof, are coupled to the defibrillating device. A displacement sensor could be used to measure or infer the depth of chest compression. Some defibrillating devices administer defibrillation in synchrony with external chest compressions detected through the force sensor, motion sensor, displacement sensor, or accelerometer. Other defibrillation devices deliver pacing in synchrony with external chest compressions detected through the force sensor, motion sensor, displacement sensor, or accelerometer.

One defibrillating device according to the present invention includes a defibrillator module for defibrillating a person, at least one sensor which can output a signal, and a controller coupled to the sensor, in which the controller executes logic for deducing whether a therapy is being performed on the person based at least in part on the sensor signal, where the therapy is not being performed by the defibrillating device. Some controllers vary operation of the defibrillating device responsive to the deduced therapy, which can include varying
operation of the defibrillator module responsive to the deduced therapy. Some
devices further comprise at least one human interface module for accepting input
from a human operator, in which the human interface module accepts human
entered confirmation of the deduced therapy. Devices may include the human
interface module accepting voice input and/or manual input. Some defibrillating
device controllers vary defibrillating responsive to the therapy deduced, and may
inhibit generation of a defibrillation pulse responsive to awareness of the therapy.

The present invention provides a defibrillating device comprising means for
defibrillating a person, and means for the defibrillating device becoming aware of
a therapy being performed on the person, where the therapy is not being
performed by the defibrillating device. The device can also include means for
varying operation of the defibrillating device responsive to the means for
becoming aware of the therapy. In some devices, means for varying operation of
the defibrillating device include means for varying operation of the means for
defibrillating. The means for becoming aware of another therapy can include
means for accepting human input, which can include means for accepting human
voice input, which can include a data input device accepting manual input.

In other devices, the means for varying operation of the defibrillating device
can defibrillate the person. The means for varying operation of the defibrillating
device may decide not to defibrillate the person responsive to the means for
becoming aware of the therapy. Some devices also include means for generating
instructions to a human assistant, for example, instructions to administer chest
compression on the patient. The means for becoming aware of the therapy may
include means for deducing the therapy from at least one sensor signal. Some
devices include means for confirming the deducing using human input.

The present invention also provides methods for treating a person
comprising causing a defibrillating device to query whether a therapy is being
performed on the person that is not being performed by the defibrillating device.
Some methods include causing the defibrillating device to query a sensor coupled
to the defibrillating device and to deduce whether the therapy is being performed
based at least in part on the sensor query. Other methods include querying a
human near the defibrillating device to confirm the deduced therapy. In still other
methods, the query includes causing the defibrillating device to query a human near the defibrillating device and causes the defibrillating device to deduce whether the therapy is being performed based at least in part on the human query. Defibrillation may be performed or inhibited responsive to the query.

Some methods provided by the present invention include receiving an input that a person is receiving therapy and generating instructions to operate a defibrillator to defibrillate the person responsive to the input. Such methods can also include generating instructions to deduce whether the person is receiving the therapy based at least in part on the input received. The receiving input may include receiving a sensor signal and/or a human entered input. Methods can also include generating instructions to query whether the person is receiving the therapy and/or to request human confirmation that the person is receiving the deduced therapy. Instructions may be generated to initiate defibrillation responsive to the deduced therapy.

In some methods, the sensor signal includes chest compression information, and instructions are generated to initiate defibrillation and/or pacing in synchrony with the chest compression information. The input that the person is receiving therapy may be input by a human, and may be input using voice inputs. Instructions may be generated to generate voice outputs to inform a human of the therapy.

The present invention also includes an article comprising a storage medium, the storage medium having instructions stored thereon, in which when the instructions are executed by at least one device, they result in, receiving an input that a person is receiving therapy, and generating instructions to operate a defibrillator to defibrillate the person responsive to the input.

**Description of the Drawings**

Fig. 1 is a conceptual block diagram of a defibrillator made according to the present invention in various combined embodiments;

Fig. 2 shows devices that can be applying other therapy to the patient of Fig. 1;

Fig. 3 is a block diagram of possible features of the defibrillator of Fig. 1;

Fig. 4 is a diagram of an electrode embodiment of the defibrillator of Fig. 3;
Fig. 5 is a diagram illustrating additional optional camera and telemedicine features of the invention;

Fig. 6 is a conceptual block diagram of the defibrillator of Fig. 1, receiving possible patient inputs, for example using the features of Fig. 3;

Fig. 7 is a conceptual block diagram of the defibrillator of Fig. 1 inferring the other therapy received by a patient from the received patient inputs;

Fig. 8 is a block diagram illustrating an I/O module of the defibrillator of Fig. 1;

Fig. 9 is a block diagram for illustrating the relationship of software embodiments of the present invention;

Fig. 10 is a flowchart illustrating a method according to a main embodiment of the present invention;

Fig. 11 is a time diagram showing detected signals, inferred other therapy (chest compressions), and coordinated electrotherapy by the defibrillator of Fig. 1;

Fig. 12 is a flowchart illustrating a method according to another embodiment of the present invention;

Fig. 13 is a flowchart segment illustrating an optional pacing portion of the flowchart of Fig. 12; and

Fig. 14 is a view of a sample screen from an operation of the invention.

**Detailed Description of the Preferred Embodiments**

Figure 1 illustrates system 40 which can include performing defibrillation and other therapies on a person or patient 42. A defibrillator 50 includes an input portion 52 for learning of and being performed on person 42. A human interface device or user interface device 55 can provide a user interface to defibrillator 50.

User interface 55 can include an output portion 54 generated by defibrillator 50 for the benefit of a human assistant or operator. User interface portion 54 can include any suitable output medium, including but not limited to, voice and visual display. Output portion 54 can be used to inform a human assistant of the other therapy or therapies detected or inferred by defibrillator 50. Output portion 54 can also be used to generate instructions or advice to a human assistant.

User interface 55 can also include an input portion 56. Input portion 56 can receive direct information from a human assistant about another therapy being
performed, and can also be used to receive confirmation from a human assistant that other therapy is being performed. Input portion 56 can further be used to enter data relevant to the situation of the person, for example, the length of time the patient has been unresponsive, the size or approximate age of the person, or other relevant attributes. Input portion 56 can include any suitable audio, visual or manually operable input. Voice recognition, touch screens, knobs, dials, levers, and keyboard entries are non-limiting examples of some data input elements that can be included.

In addition to the human assistant inputs and outputs provided by human interface device 55, defibrillator 50 can also provide a patient input portion 46 and a patient output portion 47. Patient input portion 46 can include direct measurements of patient physiological data as well as direct measurement of attributes that may be indicative of the other therapy or therapies being performed on person 42. Defibrillator 50 can also include an output portion 47 for delivering electrotherapy to person 42. Electrotherapy 47 can include defibrillation and, optionally, pacing. Electrotherapy output 47 can be optimized, after defibrillator 50 becomes aware of another therapy or therapies being performed on person 42.

Another therapy or therapies, represented generally at 44, may be being performed on person 42. Other therapies 44 may be performed by the human assistant, other assistants, or by other automatic devices apart from defibrillator 50.

In general, electrotherapy is an electrical shock, directed through the heart of the patient by externally applied electrodes. This has been shown to defibrillate the heart, for restoring its rhythm.

The other therapy, represented at 44, may be applied by the rescuer directly, or by a machine. Another therapy could be initially independent, but later coordinated as part of the invention. Examples of such machines are now described.

Figure 2 illustrates some other devices that could be used in applying the other therapy 44 of Figure 1. One such device includes an external chest compression (ECC) device 60 that can include a back frame 61 and include moveable members 62 for applying external chest compression. Members 62
maybe applied in a number of configurations, for example, pivotally mounted rigid chest compression members, contractible or retractable vests, contractible or retractable belts, or other suitable chest compression members well known to those skilled in the art. Compressing and releasing may be performed according to any type of profile. One such profile may be seen in Figure 11. Other profiles may be sine-wave shaped, triangular shaped, or other shaped.

Another therapy may be ventilation of the patient. A ventilator 64 is represented generally in Figure 2. If the ventilation is by a human, defibrillator 50 may issue prompts for instructing the rescuer. The prompts may be timed. The rescuer may either be performing mouth-to-mouth resuscitation, or operating a bag valve mask device where the user manually squeezes the bag. If the ventilator is to be automatic, a tube can be inserted into the patient’s mouth, and a pump used. A mask may also be on the face of the patient. The oxygen can be delivered this way to the patient. Other devices, such as valves that block the airway during chest decompression (for example, CPR-x valve) can be included in the ventilation portion of a device. To the extent it is automatic, a pump of the ventilation portion may be advantageously integrated with the back frame to provide the other therapy.

Yet other devices for applying other therapy to the patient include a cooling module 66 to induce hypothermia. Cooling module 66 may include a canister 68 for containing a liquid that can expand to a gas and provide cooling upon its release. Cooling module 66 can also include a tube 72 coupling canister 68 to a cooling garment 70, which can be disposed over the person to be cooled.

Figure 3 illustrates defibrillator 50 of Figure 1 that may have any range of additional possible features and functionalities. For example, the defibrillator of the invention may be implemented as an Automatic External Defibrillator (AED). In that case, it can have electrodes 80 and 82 that can be used to measure the patient impedance, represented at 84. Defibrillator 50 can further have several ECG leads 86 that can be used to measure the ECG signals of the patient. A variety of sensors, for example, sensors 90 and 92 can also be coupled to defibrillator 50. Sensors can measure such physiological attributes as pulse, respiration, oximetry, or other attributes. A temperature sensor or thermometer 94
can also be coupled to defibrillator 50. Data from the electrodes, leads and sensors can be used to directly measure or infer another therapy or therapies being performed on the person.

Figure 4 illustrates another sensor that can be coupled to defibrillator 50. The sensor includes a defibrillator electrode 100 having a pressure sensor 102 affixed to the defibrillator electrode. A wire 104 or other signal-carrying medium may be used to carry the signal from pressure sensor 102 to defibrillator 50. The pressure of any externally applied chest compressor can be measured using pressure sensor 102. For example, the electrodes may be implemented with springs, or Piezo electric sensors. These are preferably placed under the chest compression members of the chest compression device of Figure 2.

Figure 5 illustrates additional, optional features of the invention. The invention advantageously includes a camera 112. Camera 112 is preferably a digital camera, and may be either video or still. The camera may be advantageously attached to a post 111 on defibrillator 50. This permits recording of the scene and patient. The recording may be used for record keeping, event analysis, and other purposes. Alternately, the recording may be used for live transmission to a remote assistance center 120, from where trained medical personnel can, in turn, provide feedback. Transmission can take place as described below.

Continuing to refer to Figure 5, the invention preferably and advantageously includes a communications module 110 capable of establishing a communication link 114 with an antenna 116. Antenna 116 can communicate via a network 118 with remote assistance center 120. In a preferred embodiment, communication module 110 includes the functionality of a portable telephone, and network 118 is a network that supports voice and/or data communications.

The user of the invention can establish a communication link with remote assistance center. Then the information transmitted can include images, if a camera is provided, and the patient's vital signs that can be encoded by the invention for communication. The information transmitted can also include the rescuers comments, observations, and even questions.
In some embodiments, the invention is operable from the remote assistance center. An operator at the remote assistance center can transmit through the communication link 118 a command code, and the invention operated accordingly. Such operation may actually include defibrillation.

Moreover, the monitored data, including also recorded data such as events and waveforms, may be also transmitted to a system for collecting or storing patient information and to a computer-aided dispatch system for assistance. Furthermore, it may be sent to a billing system for determining patient billing.

Figure 6 illustrates defibrillator 50 receiving a variety of patient inputs 130. Inputs 130 can be detected by, and received into, defibrillator 50. These may be known, for example, using the features of Figure 3. Patient inputs can include impedance, for example, measured by electrodes. Another input includes external chest pressure as measured from electrodes or a chest pressure sensor. ECG signals can be provided by leads to defibrillator 50. Inputs 130 can also include pulse detection, respiration detection, motion detection, pulse oximetry detection, and temperature.

Figure 7 illustrates a variety of other independent therapies 140 that can be inferred from analyzed patient inputs. The other independent therapies 140 can be processed in defibrillator portion 53 that can include a central processing unit or other processor. One other therapy is chest compression, which can be inferred from an impedance time profile, an artifact in the ECG signal, pressure on electrodes, motion detection (periodicity), and/or signal detection. Another independent therapy is ventilation, which can be inferred from respiration detection. Yet another therapy is cooling, that can be inferred from a temperature measurement of the person.

Referring to Fig. 8, the defibrillator of the invention preferably also includes a computer or processor 150 and an Input/Output (I/O) module or user interface module 152. The defibrillator has input devices such as keys, switches, knobs, levers, a microphone for voice recording and preferably also voice recognition etc., and output devices such as one or more screens, a speaker, a printer, etc. All these are preferably aggregated at the I/O module (e.g. using a keypad), but
that is not necessary for practicing the invention. They may be located elsewhere in the device, or received wirelessly, etc.

The I/O module is used as a user interface. In some embodiments of the invention, when the defibrillator of Fig. 1 has inferred that another therapy is being applied independently, it informs the user. Further, it may ask for confirmation. In other embodiments of the invention, the interface is used so that the defibrillator of the invention learns directly of the other therapy being applied independently. In those embodiments, the defibrillator of the invention learns about the other therapy directly from the user.

The present invention may be implemented by one or more devices that include logic circuitry. The device performs functions and/or methods as are described in this document. The logic circuitry may include a processor that may be programmable for a general purpose, or dedicated, such as microcontroller, a microprocessor, a Digital Signal Processor (DSP), etc. For example, the device may be a digital computer like device, such as a general-purpose computer selectively activated or reconfigured by a computer program stored in the computer. Alternately, the device may be implemented as an Application Specific Integrated Circuit (ASIC), etc. These features are integrated with the invention, or are coupled with it.

Moreover, the invention additionally provides methods, which are described below. The methods and algorithms presented herein are not necessarily inherently associated with any particular computer or other apparatus. Rather, various general-purpose machines may be used with programs in accordance with the teachings herein, or it may prove more convenient to construct more specialized apparatus to perform the required method steps. The required structure for a variety of these machines will become apparent from this description.

In all cases there should be borne in mind the distinction between the method of the invention itself and the method of operating a computing machine.

The present invention relates both to methods in general, and also to steps for operating a computer and for processing electrical or other physical signals to generate other desired physical signals.
The invention additionally provides programs, and methods of operation of the programs. A program is generally defined as a group of steps leading to a desired result, due to their nature and their sequence. A program made according to an embodiment of the invention is most advantageously implemented as a program for a computing machine, such as a general-purpose computer, a special purpose computer, a microprocessor, etc.

The invention also provides storage media that, individually or in combination with others, have stored thereon instructions of a program made according to the invention. A storage medium according to the invention is a computer-readable medium, such as a memory, and is read by the computing machine mentioned above.

The steps or instructions of a program made according to an embodiment of the invention require physical manipulations of physical quantities. Usually, though not necessarily, these quantities may be transferred, combined, compared, and otherwise manipulated or processed according to the instructions, and they may also be stored in a computer-readable medium. These quantities include, for example electrical, magnetic, and electromagnetic signals, and also states of matter that can be queried by such signals. It is convenient at times, principally for reasons of common usage, to refer to these quantities as bits, data bits, samples, values, symbols, characters, images, terms, numbers, or the like. It should be borne in mind, however, that all of these and similar terms are associated with the appropriate physical quantities, and that these terms are merely convenient labels applied to these physical quantities, individually or in groups.

Referring also to Fig. 9, a general computer or processor 160 is shown, having a memory 162. A program 164 may reside on the memory according to the invention. Further, a data storage device, (computer readable medium) 166 may be interfaced with the computer, to transfer data that may define a program. The general computer of Fig. 9 may be implemented by a CPU, and preferably interfaces with the I/O module.

This detailed description is presented largely in terms of flowcharts, display images, algorithms, and symbolic representations of operations of data bits within
at least one computer readable medium, such as a memory. An economy is achieved in the present document in that a single set of flowcharts is used to describe both methods of the invention, and programs according to the invention. Indeed, such descriptions and representations are the type of convenient labels used by those skilled in programming and/or the data processing arts to effectively convey the substance of their work to others skilled in the art. A person skilled in the art of programming may use these descriptions to readily generate specific instructions for implementing a program according to the present invention.

Often, for the sake of convenience only, it is preferred to implement and describe a program as various interconnected distinct software modules or features, individually and collectively also known as software and softwares. This is not necessary, however, and there may be cases where modules are equivalently aggregated into a single program with unclear boundaries. In any event, the software modules or features of the present invention may be implemented by themselves, or in combination with others. Even though it is said that the program may be stored in a computer-readable medium, it should be clear to a person skilled in the art that it need not be a single memory, or even a single machine. Various portions, modules, or features may reside in separate memories, or even separate machines. The separate machines may be connected directly, or through a network, such as a local access network (LAN), or a global network, such as the Internet.

It will be appreciated that some of these methods may include software steps which may be performed by different modules of overall parts of a software architecture. For example, data forwarding in a router may be performed in a data plane, which consults a local routing table. Collection of performance data may also be performed in a data plane. The performance data may be processed in a control plane, which accordingly may update the local routing table, in addition to neighboring ones. A person skilled in the art will discern which step is best performed in which plane.

In the present case, methods of the invention are implemented by machine operations. In other words, embodiments of programs of the invention are made such that they perform methods of the invention that are described in this
document. These may be optionally performed in conjunction with one or more human operators performing some, but not all of them. As per the above, the users need not be collocated with each other, but each only with a machine that houses a portion of the program. Alternately, some of these machines may operate automatically, without users and/or independently from each other.

Methods of the invention are now described.

Referring now to Fig. 10, a flowchart 1900 is used to illustrate a method according to a main embodiment of the invention. The method of flowchart 1900 may be practiced as an additional method to another protocol, and may also be practiced by the defibrillator of Fig. 1.

According to a box 1910, it is inquired whether the patient is receiving other therapy. At least two paths may then be followed.

First, according to a next box 1920, received signals are analyzed, for example for periodicity and also as described elsewhere in this document.

According to an optional intermediate box 1930, a confirmation may be requested from the user via the interface. Then execution proceeds to a routing box 1940, depending on whether other therapy has been received and/or confirmed.

Alternately, according to another box 1950, an inquiry is issued to the user at the interface. The user may be asked, for example, at the screen: “IS THERE ANOTHER DEVICE TREATING THE PATIENT?” According to a next box 1960, a reply is received (YES/NO), and then again execution proceeds to routing box 1940.

If at box 1940 it is determined that no other therapy is taking place, then according to a next box 1970, the defibrillator may proceed according to any other protocol, e.g. a known protocol.

Otherwise, according to a next box 1980, coordinated therapies are implemented, such as is described below.

Referring briefly to Fig. 11, a time profile of detected signals is shown. More particularly, the main level of the patient impedance is plotted in time.

(Other impedance variations may be superimposed on the main level of impedance).
In addition, the externally measured chest pressure is shown, if available. These patterns indicate that CPR is being performed. The inference may be confirmed by asking the user.

Advantageously, defibrillation (the large lightning bolts in Fig. 11) may take place any time in the CPR cycle. The exact timing is chosen in synchronization to pursue various optimizations. For example, if it is desired to exploit the smallest possible impedance, defibrillation happens according to bolt (A). On the other hand, if it is desired to exploit the moment that the heart is filled with the most blood (and thus draw the most current through the heart), then defibrillation happens according to bolt (B).

CPR may continue after defibrillation, or even be halted after it. An advantage of the invention is that the waiting time between CPR and defibrillation is minimized. Pacing takes place as described later in this document.

Referring now to Fig. 12, a flowchart 2300 is used to illustrate a method according to an embodiment of the invention. The method of flowchart 2300 may also be practiced by the devices of the invention described in this document. Above and beyond the method described herein, the responder (who is also a user) may be instructed on how to apply a device, and or interactively give feedback, and/or to perform steps of the method, etc.

According to a box 2310, signals are received about the patient, and optionally are also monitored. Optionally, they are also recorded, displayed, transmitted, etc.

The signals are received from the patient (such as ECG), from special sensors (such as oximetry, impedance, force, etc.). Signals may also be received from the responder interactively, e.g. by asking questions and receiving answers. The signals are then analyzed and treated as inputs.

The process of box 2310 preferably takes place continuously, even if execution moves also to other boxes of flowchart 2300. Plus, there can be different stages of monitoring, such as main monitoring, at exact box 2310, and secondary monitoring concurrent with other stages, e.g. at the same time as any one of boxes 2330, 2340, 2380 below.
In addition, monitoring may be also for detecting Acute Myocardial Infarction (AMI), via the ECG or other monitoring parameters, and indicating this to the caregiver. If AMI is detected, then monitoring may also be for cardiac arrest (which commonly occurs during an AMI).

In addition to monitoring, preferably there is also recording. The accumulated record may include records of events, data monitored, and features of the invention that are operating, and time profiles of their operation.

A number of decision trees may then be implemented, in determining what action to take next. The best embodiments known to the inventors are described, but that is only by way of example, and not of limitation. Further, the flowchart may be integrated with other steps, such as administering medications (e.g. cardiac drugs), etc. But simplistically, the ECG input is analyzed for a shockable rhythm, and then either defibrillation takes place, or pulse or other signs of circulation are checked, following the same protocol as in today’s AEDs. Further, a user would be prompted to start chest compressions and ventilations if there was no pulse (or no signs of circulation), or cooling, etc. A more rigorous way is described below.

According to a next box 2320, it is determined whether Ventricular Fibrillation (VF) of the patient’s heart is occurring. If so, then according to a next box 2330, the patient is defibrillated. This is accomplished by administering electrotherapy, such as a defibrillation shock. If a child ("pediatric") patient is sensed, then the defibrillation energy level may be adapted automatically (e.g. be set to 50J). Such sensing may be from responder inputs, the belt or vest size when tightened around the patient, etc.

In yet other embodiments, based on the length of time the patient has been unresponsive (which could be entered into the device by the caregiver), or by analysis of parameter that indicates probability of shock success (such as ECG), it may first be decided whether to deliver electrotherapy, or to first instruct to perform CPR, and/or to first deliver medications prior to defibrillating. That action could either be started automatically by the system, or could be started with manual action from the user.
Execution may then return to box 2310, where inputs are received and analyzed. In a preferred optional embodiment, however, according to a next box 2340, Cardiopulmonary Resuscitation (CPR) is performed after defibrillating. That may be by instructing to start it, or to permit it to continue taking place automatically, as it may be monitored. Instruction may be by voice commands, and/or may include sounds for the responder to synchronize their action. Execution returns to box 2310.

Alternately, as seen above in Fig. 11, boxes 2330 and 2340 take place together. In other words, defibrillation takes place while CPR is being performed automatically.

Returning to Fig. 12, if, at box 2320 it is determined that the patient is not undergoing VF, then according to an optional next box 2350, it is inquired whether a pulse is detected. If not, then according to an optional next box 2360, it is inquired whether the condition of Ventricular Tachycardia (VT) is detected. If so, then execution reverts to box 2330, and the patient is defibrillated. But if no VT is detected at box 2360, then execution reverts to box 2340 for performing CPR.

If a pulse is detected at box 2350, then, according to an optional next box 2370, it is inquired whether respiration is detected. If so, then execution returns to box 2310. Respiration may be detected automatically by respiration sensors, such as a CO2 (carbon dioxide) sensor, a chest movement sensor, or electrodes for measuring impedance.

If at box 2370 there is no respiration detected, then according to an optional next box 2380, ventilation is instructed for the responder. That may be by either engaging an automatic ventilator, or by performing rescue breathing.

Execution returns to box 2310.

Since box 2310 is preferably executed continuously, the method also includes discontinuing one type of therapy, and optionally also starting another consistently with the above. Also, if one of the vital signs changes, execution may return to box 2310 and start over. For example, pulse may be lost while ventilating. Or the onset of respiration may detected, in which case other activities (such as ventilation) stop.
Referring now to optional box 2390, optional pacing according to the invention is also described. In the embodiment of Fig. 12, the condition for enabling pacing is examined in two circumstances, namely in transitioning from box 2350 to 2370, and also in transitioning from box 2360 to 2340.

Referring now to Fig. 13, box 2390 is described in more detail. In both cases, it is inquired whether severe bradycardia is detected. In addition, in no pulse has been detected, it is inquired whether ventricular asystole has been detected. If not, then execution continues as before (from box 2350 to 2370, and from box 2360 to 2340). If yes, then according to a box 2395, pacing is performed.

Returning to Fig. 11, pacing (shown as a small lightning bolt) may also be coordinated with the administration of CPR. Pacing is preferably synchronized with the compression cycle. There is some evidence that chest compressions may cause a QRS complex (ventricular depolarization), if the heart is able to support it. Accordingly, pacing during the compression cycle provides the additional impetus to the ventricles. Also, pacing should be avoided a few 100 msec after a QRS complex, during the ventricular vulnerability period.

At any one time during the method of Fig. 12, inputs are received (for monitoring) from the available sensors, and from the user through the I/O module. Outputs are communicated to the user through the I/O module.

Referring now to Fig. 14, a sample screen is shown for communicating to the user the outputs. In the example of Fig. 14, there is a count down for imminent defibrillation (at the 3 sec point).

A person skilled in the art will be able to practice the present invention in view of the description present in this document, which is to be taken as a whole. Numerous details have been set forth in order to provide a more thorough understanding of the invention. In other instances, well-known features have not been described in detail in order not to obscure unnecessarily the invention.

While the invention has been disclosed in its preferred form, the specific embodiments as disclosed and illustrated herein are not to be considered in a limiting sense. Indeed, it should be readily apparent to those skilled in the art in view of the present description that the invention may be modified in numerous
ways. The inventor regards the subject matter of the invention to include all combinations and sub combinations of the various elements, features, functions and/or properties disclosed herein.
Claims

1. A defibrillating device comprising:
   a defibrillator module for defibrillating a person; and
   at least one human interface module for accepting input from a human
   operator, in which the human interface module accepts human entered indications
   of a therapy being performed on the person, where the therapy is not being
   performed by the defibrillating device.

2. A device as in claim 1, further comprising a controller coupled to the human
   interface module for varying operation of the defibrillating device responsive to the
   human input.

3. A device as in claim 2, in which the controller varies operation of the
   defibrillator module.

4. A device as in claim 1, in which the human interface module includes a
   voice input module.

5. A device as in claim 1, in which the human interface module includes a
   manual input module to accept manually input data.

6. A device as in claim 2, in which the defibrillating device controller varies
   defibrillating responsive to the indication of the therapy.

7. A device as in claim 2, in which the defibrillating device controller inhibits
   generation of a defibrillation pulse responsive to the indication of the therapy.

8. A device as in claim 1, in which the defibrillating device can generate
   instructions to a human assistant.

9. A device as in claim 8, in which the defibrillating device can generate
   instructions to administer chest compression on the patient.

10. A device as in claim 1, further comprising a respiration sensor coupled to
    the defibrillating device.

11. A device as in claim 1, further comprising a sensor selected from the group
    consisting of force sensors, accelerometers, motion sensors, and displacement
    sensors, coupled to the defibrillating device.

12. A device as in claim 1, further comprising a temperature sensor coupled to
    the defibrillating device for measuring the temperature of the person.
13. A device as in claim 1, further comprising ECG leads coupled to the defibrillating device.

14. A device as in claim 11, in which the defibrillating device administers defibrillation in synchrony with external chest compressions detected through the force sensor, accelerometer, motion sensor, or displacement sensor.

15. A device as in claim 11, in which the defibrillation device delivers pacing in synchrony with external chest compressions detected through the force sensor, accelerometer, motion sensor, or displacement sensor.

16. A defibrillating device comprising:

   means for defibrillating a person; and

   means for the defibrillating device becoming aware of a therapy being performed on the person, where the therapy is not being performed by the defibrillating device.

17. A device as in claim 16, further comprising means for varying operation of the defibrillating device responsive to the means for becoming aware of the therapy.

18. A device as in claim 17, in which the means for varying operation of the defibrillating device includes means for varying operation of the means for defibrillating.

19. A device as in claim 16, in which the means for becoming aware of the therapy includes means for accepting human input.

20. A device as in claim 16, in which the means for becoming aware of the therapy includes means for accepting human voice input.

21. A device as in claim 16, in which the means for becoming aware of the therapy includes a data input device accepting manual input.

22. A device as in claim 16, in which the means for varying operation of the defibrillating device can defibrillate the person.

23. A device as in claim 16, in which the means for varying operation of the defibrillating device can decide not to defibrillate the person responsive to the means for becoming aware of the therapy.

24. A device as in claim 16, further comprising means for generating instructions to a human assistant.
25. A device as in claim 24, further comprising means for generating instructions to administer chest compression on the patient.
26. A device as in claim 24, further comprising means for generating instructions to ventilate the patient.
27. A device as in claim 17, in which the means for becoming aware of the therapy includes means for deducing the therapy from at least one sensor signal.
28. A device as in claim 27, further comprising means for confirming the deducing using human input.
29. A device as in claim 17, further comprising means for detecting respiration.
30. A device as in claim 17, further comprising means for detecting pulse.
31. A device as in claim 17, in which the means for becoming aware of the therapy includes means for detecting external chest compression.
32. A device as in claim 17, in which the means for becoming aware includes means for detecting cooling of the person.
33. A device as in claim 17, in which the means for becoming aware of the therapy includes means for measuring thoracic impedance.
34. A device as in claim 17, further comprising means for measuring ECG signals.
35. A device as in claim 17, further comprising means for administering defibrillation in synchrony with external chest compressions.
36. A method for treating a person comprising causing a defibrillating device to query whether a therapy is being performed on the person that is not being performed by the defibrillating device.
37. A method as in claim 36, in which the query includes causing the defibrillating device to query a sensor coupled to the defibrillating device and to deduce whether the therapy is being performed based at least in part on the sensor query.
**Fig. 6**

DETECTED/RECEIVED PATIENT INPUTS

IMPEDEANCE (FROM ELECTRODES)
EXT. CHEST PRESSURE (FROM ELECTRODES)
ECG (FROM LEADS)
PULSE DETECTION
RESPIRATION DETECTION
MOTION DETECTION
PULSE OXIMETRY DETECTION
TEMPERATURE

**Fig. 7**

OTHER INDEPENDENT THERAPY INFERRED FROM ANALYZED PATIENT INPUTS:

CHEST COMPRESSIONS, FROM:
IMPEDEANCE TIME PROFILE
ARTIFACT IN ECG SIGNAL
PRESSURE ON ELECTRODES
MOTION DETECTION (PERIODICITY)
SIGNAL DETECTION

VENTILATION, FROM:
RESPIRATION DETECTION

COOLING, FROM:
THERMOMETER
1900

INQUIRE WHETHER PATIENT IS RECEIVING OTHER THERAPY

1910

ISSUE INQUIRY AT INTERFACE

1920

ANALYZE RECEIVED SIGNALS

1930

REQUEST/RECEIVE CONFIRMATION VIA INTERFACE

1940

ROUTING BOX: OTHER THERAPY BEING RECEIVED?

1950

RECEIVE REPLY

1960

COORDINATE THERAPIES

1970

PROCEED AS PER PROTOCOL

1980

NO
**Fig. 11**

MEASURED MAIN LEVEL OF IMPEDANCE

MEASURED CHEST PRESSURE

INFERRED CHEST COMPRESSIONS
[C - COMPRESS]
[R - RELEASE]

SYNC'ED DEFIBRILLATION

SYNC'ED PACING

TIME

C R C R
Fig. 12

2310 MONITOR SIGNALS; RECORD; ANALYZE

2320 VF DETECTED?

NO

2350 PULSE DETECTED?

YES

2360 VT DETECTED?

NO

2390 DEFIBRILLATE

YES

2340 INSTRUCT CPR

2370 RESPIRATION DETECTED?

YES

2380 INSTRUCT RESPIRATION

NO
**Fig. 13**

2390 SEVERE BRADYCARDIA DETECTED? (E.G <40BPM)
VENTRICULAR ASYSTOLE DETECTED?

NO (AS BEFORE) YES

2395 PACE

**Fig. 14**

INTERFACE

[VITAL SIGNS]

DETECTED COMPRESSION PROFILE:

WILL BE DEFIBRILLATING IN 0:03

STAND CLEAR
**INTERNATIONAL SEARCH REPORT**

A. CLASSIFICATION OF SUBJECT MATTER

| IPC | A61N1/39 | A61B5/0205 |

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

| IPC | A61N | A61B | A61H |

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the international search (name of database and, where practical, search terms used)

**EPO-Internal**

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>column 3, line 15 - column 6, line 51; figures 1-5</td>
<td></td>
</tr>
</tbody>
</table>

| X | Further documents are listed in the continuation of box C. |
| X | Patent family members are listed in annex. |

---

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

* "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* "S" document member of the same patent family

Date of the actual completion of the international search: 6 July 2004
Date of mailing of the international search report: 14/07/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5815 Patentlaan 2 NL-2280 HV Rijswijk
Tel.: (+31-70) 940-2040, Tx. 31 651 epo nl, Fax: (+31-70) 940-3016

Authorized officer: Fischer, O
<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 6 021 349 A (FORMAN NANCY H ET AL) 1 February 2000 (2000-02-01)</td>
<td>1-3, 5-8, 13, 16-19, 21-24, 27, 30, 34, 4, 9-12, 14, 15, 20, 25, 26, 28, 29, 31-33, 35</td>
</tr>
<tr>
<td>A</td>
<td>column 2, line 1 -column 6, line 67; figures 1-7B</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X</td>
<td>US 4 610 254 A (ROBERTS DOUGLAS H ET AL) 9 September 1986 (1986-09-09)</td>
<td>1-3, 5-10, 13, 16-19, 21-25, 27, 29-31, 33, 34, 4, 11, 12, 14, 15, 20, 26, 28, 32, 35</td>
</tr>
<tr>
<td>A</td>
<td>column 4, line 10 -column 5, line 45; figures 1-4B</td>
<td></td>
</tr>
</tbody>
</table>

Form PCT/IBA/210 (continuation of second sheet) (January 2004)
INTERNATIONAL SEARCH REPORT

Box II Observations where certain claims were found unreadable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 36–37
   because they relate to subject matter not required to be searched by this Authority, namely:
   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. ☐ Claims Nos.:
   because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest
☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.
<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
<th>Publication date</th>
</tr>
</thead>
</table>