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(71) Applicant: **KONINKLIJKE PHILIPS N.V.** [NL/NL]; High Tech Campus 5, NL-5656 AE Eindhoven (NL).

(72) Inventor: **HERLEIKSON, Earl Clark**; c/o High Tech Campus 5, NL-5656 AE Eindhoven (NL).

(74) Agents: **STEFFEN, Thomas** et al.; High Tech Campus Building 5, NL-5656 AE Eindhoven (NL).

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(54) Title: SYNCHRONIZED CARDIOVERSION MIXED MODE OPERATION AND TIMING VERIFICATION

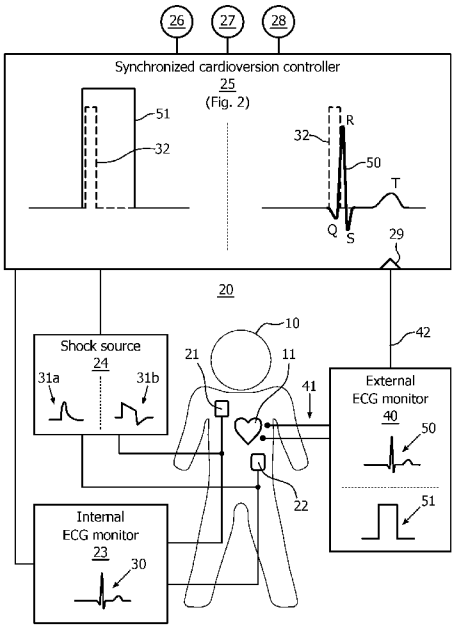


FIG. 1

(57) Abstract: A defibrillator system employs an external ECG monitor (40) and a defibrillator (20). In operation, external ECG monitor (40) generates a synchronized cardioversion input signal as one of an external ECG waveform (50) of a heart (11) of a patient (10) or an external synchronized pulse (51) indicative of a detection by the external ECG monitor (40) of at least one QRS complex of the external ECG waveform (50). Defibrillator (40) includes a synchronized cardioversion input channel (29) for receiving the synchronized cardioversion input signal from external ECG monitor (40), and controls a conditional delivery of a defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the defibrillator (20) receiving the synchronized cardioversion input signal. One condition for shock delivery is a measured time delay between an internal ECG waveform (30) and the synchronized cardioversion input signal being less than a baseline time delay.

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# Synchronized Cardioversion Mixed Mode Operation And Timing Verification

The present invention generally relates to a synchronized cardioversion mode of a defibrillator. The present invention specifically relates to the synchronized cardioversion mode of the defibrillator providing (1) a mixed mode operation involving an external ECG monitor communicating a synchronized cardioversion input signal in the form of an ECG waveform or a synchronized pulse, and (2) a timing verification preventing an excessive time delay between an internal ECG waveform and the synchronized cardioversion input signal for purposes of executing a synchronized cardioversion.

Historically, synchronized cardioversion has been used to stop atrial fibrillation of a patient's heart. Specifically, during atrial fibrillation, ventricles of the patient's heart are continuing to contract, which produces an organized heartbeat that is capable of sustaining the patient's life. Nonetheless, atrial fibrillation typically results in an erratic heat rhythm and a failure to stop atrial fibrillation allows blood to pool in the atria of the heart, which can lead to blood clots that can further lead to a stroke.

A synchronized cardioversion method of terminating atrial fibrillation is with a defibrillation shock to the patient's heart that is synchronized with contractions of the ventricles in order to minimize risk that the defibrillation shock could cause ventricular fibrillation of the patient's heart, which is not capable of sustaining the patient's life. More particularly, without synchronization of the defibrillation shock to a QRS complex, the atrial defibrillation shock may occur during the repolarization of the ventricles resulting in ventricular fibrillation. Consequently, the synchronized cardioversion shock should be delivered within sixty (60) milliseconds a peak of the QRS complex in order to avoid the possibility of delivering the atrial defibrillation shock on a T-wave.

Defibrillators today usually have the capability to measure ECG directly from the patient and detect the QRS signal internally, and to deliver a synchronized cardioversion shock based on this signal. However, there are times where the clinician will prefer to use an external ECG monitor to monitor the patient and provide a signal to the defibrillator that is then used to synchronize the shock. The external ECG monitor may either supply a high level ECG analog output signal to a ECG input

channel or it may supply a high level synchronizing pulse output signal to a synchronized cardioversion input channel. Regardless of the type of output signal, as previously stated, the synchronized cardioversion shock should be delivered within sixty (60) milliseconds a peak of the QRS complex in order to avoid the possibility of delivering the atrial defibrillation shock on a T-wave. Consequently, a time delay for delivering the shock is divided between the external ECG monitor and the defibrillator.

For example, with the output being a high level synchronizing pulse and a 60 milliseconds window, the external ECG monitor is allowed 35 milliseconds to perform R-wave detection and provide the high level synchronizing pulse to the defibrillator. The defibrillator is then allowed 25 milliseconds to receive this pulse and deliver the synchronized cardioversion shock. However, there is a safety risk that the clinician may connect a high level synchronizing pulse output of the external ECG monitor to the ECG input channel of the defibrillator that is expecting a high level ECG input signal. For this scenario, the external ECG monitor is detecting the QRS complex with time delay associated with this detection that can be as high as 35 milliseconds. The defibrillator is expecting ECG data but instead is processing the high level synchronizing pulse for QRS detection. The defibrillator is not set up to properly to analyze a high level synchronizing pulse for QRS detection. Thus, there is a safety risk to the patient.

On the other hand, the clinician may connect a high level ECG output from the external ECG monitor to the synchronizing cardioversion input of the defibrillator. A defibrillator that is expecting a high level synchronizing pulse is not set up properly to analyze ECG data and correctly detect the QRS. This configuration is also a safety risk to the patient.

The present invention allows the clinician to connect either signal to the same input channel of the defibrillator by using an algorithm to discriminate between the two types of signals and processing the signals according to the type of signal. Specifically, if the signal is an ECG analog output of an external ECG monitor, then the defibrillator will use a QRS detection algorithm to trigger the synchronized pulse. Conversely, if the signal is the synchronizing pulse output of the external ECG monitor, then the defibrillator will detect this pulse with minimal time delay to trigger the synchronized pulse without the use of a QRS detection algorithm. Consequently, a risk that the

clinician may incorrectly configure synchronized cardioversion on the defibrillator using an external ECG monitor is minimized, if not eliminated. Additionally, the present invention minimizes, if not eliminates, the risk that the clinician can incorrectly deliver a shock on a T-wave resulting in ventricular fibrillation when using an external ECG monitor output for synchronizing the shock by alerting the clinician if the time delay from the external ECG monitor is excessive.

One form of the present invention is a method for a synchronized cardioversion operation by a defibrillator. The method involves the defibrillator receiving a synchronized cardioversion input signal from an external ECG monitor through an synchronized cardioversion input channel, wherein the synchronized cardioversion input signal is one of external ECG waveform of a heart of a patient or an external synchronized pulse indicative of a detection by the external ECG monitor of at least QRS complex of the external ECG waveform. The method further involves the defibrillator conditionally delivering a defibrillation shock synchronized with the synchronized cardioversion input signal to the patient in response to the defibrillator receiving the synchronized cardioversion input signal.

Conditions for delivering the defibrillation shock to the patient include, but are not limited, to (1) the defibrillator receiving and detecting the synchronized cardioversion input signal is the external ECG waveform and detecting at least one QRS complex within the external ECG waveform, particularly without any excessive time delay due to the defibrillator receiving the external ECG waveform and detecting the at least one QRS complex, and (2) the defibrillator receiving and detecting the synchronized cardioversion input signal is the synchronized pulse, particularly without any excessive time delay for the defibrillator in receiving and detecting the synchronized pulse.

A second form of the present invention is defibrillator for synchronized cardioversion employing a shock source and a controller. In operation, the controller receives a synchronized cardioversion input signal from an external ECG monitor through a synchronized cardioversion input channel, wherein the synchronized cardioversion input signal is one of an external ECG waveform of heart of a patient or an external synchronized pulse indicative of a detection by the external ECG monitor of at least one QRS complex of the external ECG waveform. The controller further

controls a conditional delivery of a defibrillation shock synchronized with the synchronized cardioversion input signal by the shock source to the patient in response to the controller receiving the synchronized cardioversion input signal.

Conditions for delivering the defibrillation shock to the patient include, but are not limited, to (1) the controller receiving and detecting the synchronized cardioversion input signal is the external ECG waveform and detecting at least one QRS complex within the external ECG waveform, particularly without any excessive time delay due to the controller receiving the external ECG waveform and detecting the at least one QRS complex, and (2) the controller receiving and detecting the synchronized cardioversion input signal is the synchronized pulse, particularly without any excessive time delay for the controller in receiving and detecting the synchronized pulse.

A third form of the present invention is defibrillation system for synchronized cardioversion employing an external ECG monitor and a defibrillator. In operation, the defibrillator receives a synchronized cardioversion input signal from the external ECG monitor through a synchronized cardioversion input channel, wherein the synchronized cardioversion input signal is one of external ECG waveform of heart of a patient or an external synchronized pulse indicative of a detection by the external ECG monitor of at least one QRS complex of the external ECG waveform. The defibrillator further controls a conditional delivery of a defibrillation shock synchronized with the synchronized cardioversion input to the patient in response to the defibrillator receiving the synchronized cardioversion input.

Conditions for delivering the defibrillation shock to the patient include, but are not limited, to (1) the defibrillator receiving and detecting the synchronized cardioversion input signal is the external ECG waveform and detecting at least one QRS complex within the external ECG waveform, particularly without any excessive time delay due to the defibrillator receiving the external ECG waveform and detecting the at least one QRS complex, and (2) the defibrillator receiving and detecting the synchronized cardioversion input signal is the synchronized pulse, particularly without any excessive time delay for the defibrillator in receiving and detecting the synchronized pulse.

The foregoing forms and other forms of the present invention as well as various features and advantages of the present invention will become further apparent from the

following detailed description of various embodiments of the present invention read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the present invention rather than limiting, the scope of the present invention being defined by the appended claims and equivalents thereof.

FIG. 1 illustrates an exemplary embodiment of a defibrillator with a mixed mode/timing verification synchronized cardioversion capabilities in accordance with the present invention.

FIG. 2 illustrates a flowchart representative of an exemplary embodiment of a mixed mode/timing verification synchronized cardioversion method in accordance with the present invention.

FIGS. 3 and 4 illustrate exemplary examples of time delay verifications in accordance with the present invention.

For purposes of the present invention, the terms "synchronized cardioversion" "unsynchronized cardioversion", "cardiac cycle", "QRS complex", "P-wave", "Q-wave", "R-wave", "S-wave", "T-wave", "QT interval", "electrode pad/paddle" and "electrocardiogram ("ECG")", "monitor", "source", "detector" and "discharger" as well as synonymous and related terms are to be broadly interpreted as known in the art of the present invention.

To facilitate an understanding of the present invention, exemplary embodiments of the present invention will be provided herein directed to a mixed mode operation and timing verification of a defibrillator in a synchronized cardioversion mode.

Referring to FIG. 1, a defibrillator 20 of the present invention employs a pair of electrode pads or paddles 21 and 22, optional ECG leads (not shown), a ECG monitor 23 (internal or external), a shock source 24, and a synchronized cardioversion controller 25.

Electrode pads or paddles 21 and 22 are structurally configured as known in the art to be conductively applied to a patient 10 in an anterior-apex arrangement as shown in FIG. 1 or in an anterior-posterior arrangement (not shown). Electrode pads or paddles 21 and 22 conduct a defibrillation shock from shock source 24 to a heart 11 of patient 10 and conduct electrical activity of heart 11 of patient 10 to ECG monitor 23. Alternatively or concurrently, ECG leads as known in the art may be connected to

patient 10 to conduct the electrical activity of heart 11 of patient 10 to ECG monitor 23.

ECG monitor 23 is structurally configured as known in the art to measure an ECG waveform 30 of heart 11 of patient 10 as an indication patient 10 is experiencing an organized heartbeat condition or an unorganized heartbeat condition. An example of ECG waveform 30 indicating an organized heartbeat condition is an ECG waveform 30 without a P-wave that is representative of an organized contraction of the ventricles of heart 11 being capable of pumping blood.

In one embodiment, ECG monitor 23 employs a digital signal processor (not shown) for streaming ECG waveform data to controller 25.

Shock source 24 is structurally configured as known in the art to store electric energy for delivery of a defibrillation shock 31 via electrode pads/paddles 21 to heart 11 of patient 10 as controlled by controller 25. In practice, defibrillation shock 31 may have any waveform as known in the art. Examples of such waveforms include, but are not limited to, a monophasic sinusoidal waveform (positive sine wave) 31a and a biphasic truncated waveform 31b as shown in FIG. 1.

In one embodiment, shock source 24 employs a high voltage capacitor bank (not shown) for storing a high voltage via a high voltage charger and a power supply upon a pressing of a charge button 26. Shock source 24 further employs a switching/isolation circuit (not shown) for selectively applying a specific waveform of an electric energy charge from the high voltage capacitor bank to electrode pads/paddles 21 as controlled by controller 25.

Controller 25 is structurally configured to execute a synchronized cardioversion in conjunction with an external ECG monitor 40 connected via a sync cable 42 to an ECG input channel 29 of controller 25.

External ECG monitor 40 is structurally configured to measure ECG waveform data of heart 11 of patient 10 as known in the art via a ECG lead set 41 conductively attached to patient 10. External ECG monitor 40 communicates an synchronized cardioversion input signal to controller 25 as one of external ECG waveform 50 of patient 10 or a synchronized pulse 51 indicative of a detection by external ECG monitor 40 of a QRS complex within the ECG waveform 50.

Controller 25 is structurally configured to utilize a pulse profile 32 for detecting whether the synchronized cardioversion input signal from external ECG monitor 40 via sync cable 42 is external ECG waveform 50 or synchronized pulse 51. Specifically, pulse profile 32 has an amplitude, a rise time and/or a duration defining a baseline synchronized pulse signal. An equivalence of synchronized cardioversion input signal to pulse profile 32 is interpreted by controller 25 as synchronized pulse signal 51 from an external ECG monitor 40. Conversely, a nonequivalence of synchronized cardioversion input signal to pulse profile 32 is interpreted by controller 25 as a ECG input signal 50 from an external ECG monitor 40. In practice, the equivalence and nonequivalence of synchronized cardioversion input signal will be dependent upon a designed functionality of defibrillator 20 and external ECG monitor 40 that must be able to distinguish between the external ECG waveform and the synchronizing pulse. In one embodiment, equivalence is defined as the synchronized cardioversion input signal having an amplitude, a rise time and a duration equal to greater than the respective amplitude, rise time and duration of the baseline synchronized pulse signal.

Controller 25 is also structurally configured to compare a baseline time delay to a measured time delay between an internal monitoring of a ECG waveform via internal ECG input monitor 23 and a reception and detection of the synchronizing cardioversion input signal via input channel 29 for determining whether a time delay between an internal ECG waveform 30 and the synchronizing cardioversion input signal is or is not excessive. In practice, the baseline time delay is preferably derived at a minimum from a sixty (60) millisecond window for external ECG monitor to generate and communicate the synchronized cardioversion input signal to controller 25 and for controller 25 to detect the input signal and deliver the synchronized cardioversion shock.

Also in practice, the measurement points of internal ECG waveform 30 and the synchronized cardioversion input signal are preferably the synchronized points for a defibrillation shock.

In one embodiment, controller 25 employ hardware/circuitry (e.g., processor(s), memory, etc.) for executing a synchronized cardioversion method of the present invention installed as software/firmware within controller 25. In practice, the software/firmware may employ a QRS detector and a shock discharger as known in the

art that are modified or revised to support an execution of the synchronized cardioversion method of the present invention.

Referring to FIG. 2, a flowchart 60 representative of the synchronized cardioversion method of the present invention executable by controller 25. The following is a description of an execution of flowchart 60 by a QRS detector 25a and a shock discharger 25b of controller 25. Please note a pressing of charge button 26 activates a storage of electric energy by shock source 24 (FIG. 1), preferably by a charging of a high voltage capacitor bank, and a pressing of shock button 27 activates a synchronized cardioversion by defibrillator 20, which may only be activated upon an arming of defibrillator 20.

A stage S62 of flowchart 60 encompasses QRS detector 25a executing a detection of each QRS complex of the ECG waveform provided by internal ECG monitor 23 and a stage S64 of flowchart 60 encompasses QRS detector 25a determining whether external ECG waveform 30 or synchronized pulse 30 is being applied to input channel 29 by external ECG monitor 40. For this determination, QRS detector 25a attempts to detect an equivalence or nonequivalence of a pulse profile 32 to the synchronized cardioversion signal.

In one embodiment, QRS detector 25a looks for a rising edge of a square pulse of the synchronized cardioversion signal prior to low pass filter of the input signal. QRS detector 25a deems the input signal to be a synchronizing pulse signal 51 if (1) an amplitude of a rising edge of the input signal is equal to or greater than an amplitude of a rising edge of the pulse profile, (2) a rise time of the rising edge of the input signal is equal to or greater than a rise time of the pulse profile, and (3) a duration of the input signal is equal to greater than a duration of the pulse profile (e.g., a maximum expected duration of a pacemaker pulse for patients that might have an implanted pacemaker). Otherwise, QRS detector 25a deems the input signal to be an external ECG waveform 30 and proceeds to a stage S66 of flowchart 60 to execute a detection of each QRS complex of external ECG waveform 30 applied to input channel 29.

For example, as shown in FIG. 1, QRS detector 25a would deem the input signal to be synchronizing pulse signal 51 in view of (1) an amplitude of a rising edge of synchronizing pulse signal 51 being greater than an amplitude of a rising edge of the pulse profile 32, (2) a rise time of the rising edge of synchronizing pulse signal 51

being greater than a rise time of pulse profile 32, and (3) a duration of the synchronizing pulse signal 51 being equal to or greater than the duration of pulse profile 32.

Otherwise, as shown in FIG. 1, QRS detector 25a would deem the input signal to be external ECG waveform 50 in view of (1) an amplitude of a rising edge of the external ECG waveform 50 being less than an amplitude of a rising edge of pulse profile 32, or (2) the rise time of the leading edge of external ECG waveform 50 being less than a rise time of the leading edge of pulse profile 32, or (3) the duration of external ECG waveform 50 being less than a duration of pulse profile 32. More particularly, the duration of pulse profile 32 is specifically needed to avoid an implanted pacemaker pulse (durations up to 2 milliseconds) from being seen by QRS detector 25a as a synchronizing pulse. QRS detector 25a is therefore configured on how an external ECG monitor 40 may represent a pacemaker pulse, which could increase the duration to about 6 milliseconds. Thus, by example, if the pulse duration requirement was set to 8 milliseconds, then QRS detector 25a could accurately determine if the input signal was a pulse or waveform for patient 10 having an implanted pacemaker.

Referring back to FIG. 2, prior to arming of shock button 27, the QRS complex detection of stage S62 is a continual process and the QRS complex detection of stage S66 is a continual process if external ECG waveform 50 was detected at ECG input 29. While the process(es) are being executed by QRS detector 25a, shock discharger 25b executes stages S68-S72 of flowchart 60 as needed to ensure a timing delay between the QRS complex detection process of stage S62 and the receipt of the synchronized cardioversion input signal at channel 29 is not excessive.

Specifically, stage S68 encompasses shock discharger 25b executing a timing verification involving a comparison of a baseline time delay to a measured time delay to determine if the measured time delay is excessive during stage S70. The baseline time delay is an acceptable added time delay to a normal time of an internal QRS complex detection of stage S68 and a delivery of a synchronized shock to patient 10 that would still comply with the overall sixty (60) millisecond requirement for synchronized cardioversion.

In one embodiment of stage 68 as shown in FIG. 3 for the external ECG waveform 50 being applied to ECG input 29, the baseline time delay is compared to a measured time delay 80 between a detection of a R peak of ECG waveform 30 by QRS detector 25a and a detection of a R peak of ECG waveform 50 by QRS detector 25a.

In a second embodiment of stage 68 as shown in FIG. 4 for the synchronized pulse signal 51 being applied to ECG input 29, the baseline time delay is compared to a measured time delay 81 between a detection of a QRS complex of ECG waveform 30 by QRS detector 25a and a detection of synchronized pulse signal 51 by QRS detector 25a.

If shock discharger 25b determines the measured time delay is excessive during stage S70 (i.e., the measured time delay is greater than the baseline time delay), then shock discharger 25b proceeds to stage S72 to communicate a time delay warning that preferably includes a lockout of shock button 27 to prohibit any delivery of a defibrillation shock.

If shock discharger 25b determines that the measured time delay is not excessive during stage S70 (i.e., the measured time delay is less than the baseline time delay), then shock discharger 25b continues to a loop of stage S68 and S70 until such time the measured time delay becomes excessive or shock button 27 is pressed.

If shock button 27 is pressed, then a stage S74 of flowchart 70 encompasses shock discharger 25b delivering the defibrillation shock to patient 10. If synchronizing pulse signal 51 was detected at stage S64, then a detection output of QRS detector 25a for triggering the shock is disabled for the duration of pulse 51 up to a maximum duration of an acceptable synchronizing pulse and shock discharger 25b synchronizes the defibrillation shock to pulse 51. Otherwise, the detection output of QRS detector 25a for triggering the shock is enabled and shock discharger 25b synchronizes the defibrillation shock to the detection output of QRS detector based on external ECG waveform 50.

Referring to FIG. 2, stages S64-66 and S74 represent a mixed mode operation of the present invention and stages S64, S68-S74 represent a timing verification of the present invention. In practice, the mixed mode operation and/or the timing verification may be individually executed or individually incorporated in other methods of delivering a defibrillation shock to a patient.

Also in practice, shock discharger 25b may execute stages S68-S72 on behalf of an external ECG monitor exclusively applying either an ECG waveform or a synchronized pulse to input channel 29.

From the description of FIG. 2, conditions for delivering the defibrillation shock to the patient include, but are not limited, to (1) the defibrillator receiving and detecting the synchronized cardioversion input signal is the external ECG data and detecting at least one QRS complex within the external ECG data, particularly without any excessive time delay due to the defibrillator receiving the external ECG data and detecting the at least one QRS complex, and (2) the defibrillator receiving and detecting the synchronized cardioversion input signal is the synchronized pulse, particularly without any excessive time delay in receiving and detecting the synchronized pulse.

Referring to FIGS. 1-4, those having ordinary skill in the art will appreciate numerous benefits of the present invention including, but not limited to, (1) minimizing a risk that a clinician can incorrectly configure synchronized cardioversion on a defibrillator using an external ECG monitor, (2) simplification of defibrillator design by providing only one input for external controlled synchronized cardioversion involving a synchronizing pulse and standard ECG signal to thereby prevent any confusion of the clinician with two different connectors for the two different inputs, and (3) minimizing a risk that the clinician can incorrectly deliver a shock on the T wave which could cause ventricular fibrillation when using an external ECG monitor output for synchronizing the shock by alerting the clinician if the delay from the external ECG monitor is excessive.

While various embodiments of the present invention have been illustrated and described, it will be understood by those skilled in the art that the embodiments of the present invention as described herein are illustrative, and various changes and modifications may be made and equivalents may be substituted for elements thereof without departing from the true scope of the present invention. In addition, many modifications may be made to adapt the teachings of the present invention without departing from its central scope. Therefore, it is intended that the present invention not be limited to the particular embodiments disclosed as the best mode contemplated for carrying out the present invention, but that the present invention includes all embodiments falling within the scope of the appended claims.

Claims

1. A defibrillator (20), comprising:

a shock source (24) structurally configured to store electric energy; and

a controller (25) including an synchronized cardioversion input channel (29) for receiving a synchronized cardioversion input signal from an external ECG monitor (40),

wherein the synchronized cardioversion input signal is one of an external ECG waveform (50) of a heart (11) of a patient (10) or an external synchronized pulse (51) indicative of a detection by the external ECG monitor (40)of at least one QRS complex of the ECG waveform, and

wherein the controller (25) is structurally configured to control a conditional delivery of a defibrillation shock synchronized with the synchronized cardioversion input signal by the shock source (24) to the patient (10) in response to the controller (25) receiving the synchronized cardioversion input signal.

2. The defibrillator (20) of claim 1, wherein the controller (25) is further structurally configured to:

detect the synchronized cardioversion input signal is the external ECG waveform (50) in response to the synchronized cardioversion input signal being nonequivalent to a pulse profile (32); and

detect the synchronized cardioversion input signal is the external synchronized pulse (51) in response to the synchronized cardioversion input signal being equivalent to the pulse profile (32).

3. The defibrillator (20) of claim 2,

wherein the controller (25) is further structurally configured to detect at least one QRS complex of the ECG waveform within the external ECG waveform; and

wherein the shock source (24) delivers the defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the controller (25) detecting the at least one QRS complex of the ECG waveform within the external ECG waveform.

4. The defibrillator (20) of claim 2,

further comprising an internal ECG monitor (23) structurally configured to generate an internal ECG waveform (30) of the heart (11) of the patient (10); and

wherein the controller (25) is further structurally configured to:

detect the least one QRS complex of the ECG waveform within the internal ECG waveform (30) and within the external ECG waveform (50);

measure a time delay between the internal ECG waveform (30) and the external ECG waveform (50); and

control a delivery by the shock source (24) of the defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the measured time delay between the internal ECG waveform (30) and the external ECG waveform (50) being less than a baseline time delay.

5. The defibrillator (20) of claim 2,

further comprising an internal ECG monitor (23) structurally configured to generate an internal ECG waveform (30) of the heart (11) of the patient (10);

wherein the controller (25) is further structurally configured to:

detect the least one QRS complex of the ECG waveform within the internal ECG waveform (30) and within the external ECG waveform (50);

measure a time delay between the internal ECG waveform (30) and the external ECG waveform (50); and

control at least one of a warning or a prohibition of a delivery by the shock source (24) of the defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the measured time delay between the internal ECG waveform (30) and the external ECG waveform (50) being greater than a baseline time delay.

6. The defibrillator (20) of claim 2, wherein the controller (25) controls a delivery by the shock source (24) of the defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the controller (25) detecting the synchronized cardioversion input signal is the external synchronized pulse (51).

7. The defibrillator (20) of claim 2,

further comprising an internal ECG monitor (23) structurally configured to generate an internal ECG waveform (30) of the heart (11) of the patient (10); and

wherein the controller (25) is further structurally configured to:

detect the least one QRS complex of the ECG waveform within the internal ECG waveform (30);

measure a time delay between the internal ECG waveform (30) and the synchronized pulse (51); and

control a delivery by the shock source (24) of the defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the measured time delay between the internal ECG waveform (30) and the synchronized pulse (51) being less than a baseline time delay.

8. The defibrillator (20) of claim 2,

further comprising an internal ECG monitor (23) structurally configured to generate an internal ECG waveform (30) of the heart (11) of the patient (10);

wherein the controller (25) is further structurally configured to:

detect the least one QRS complex of the ECG waveform within the internal ECG waveform (30);

measure a time delay between the internal ECG waveform (30) and the synchronized pulse (51); and

control at least one of a warning or a prohibition of a delivery by the shock source (24) of the defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the measured time delay between the internal ECG waveform (30) and the synchronized pulse (51) being greater than a baseline time delay.

9. A defibrillator system, comprising:

an external ECG monitor (40) structurally configured to generate an synchronized cardioversion input signal,

wherein the ECG input signal is one of an external ECG waveform (50) of a heart (11) of a patient (10) or an external synchronized pulse (51) indicative of a detection by the external ECG monitor (40)of at least one QRS complex of the ECG waveform (50); and

a defibrillator (20) including an synchronized cardioversion input channel (29) for receiving the synchronized cardioversion input signal from the external ECG monitor (40),

wherein the defibrillator (20) is structurally configured to control a conditional delivery of a defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the defibrillator (20) receiving the synchronized cardioversion input signal.

10. The defibrillation system of claim 9, wherein the defibrillator (20) is further structurally configured to:

detect the synchronized cardioversion input signal is the external ECG waveform (50) in response to the synchronized cardioversion input signal being nonequivalent to a pulse profile (32); and

detect the synchronized cardioversion input signal is the external synchronized pulse (51) in response to the synchronized cardioversion input signal being equivalent to the pulse profile (32).

11. The defibrillation system of claim 9,wherein the defibrillator (20) is further structurally configured to:

generate an internal ECG waveform (30) of the heart (11) of the patient (10);

detect the least one QRS complex of the internal ECG waveform (30);

measure a time delay between internal ECG waveform (30) and the synchronized cardioversion input signal; and

control a delivery of the defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the measured time delay between the internal ECG waveform (30) and the synchronized cardioversion input signal being less than a baseline time delay.

12. The defibrillation system of claim 9, wherein the defibrillator (20) is further structurally configured to:

generate an internal ECG waveform (30) of the heart (11) of the patient (10);

detect the least one QRS complex of the internal ECG waveform (30);

measure a time delay between internal ECG waveform (30) and the synchronized cardioversion input signal; and

executing at least one of a warning and a prohibition of a delivery of the defibrillation shock synchronized with the synchronized cardioversion input signal to the patient (10) in response to the measured time delay between the internal ECG waveform (30) and the synchronized cardioversion input signal being greater than a baseline time delay.

13. A method for a synchronized cardioversion operation by a defibrillator (20), the method comprising:

the defibrillator (20) receiving a synchronized cardioversion input signal from an external ECG monitor (40) through a synchronized cardioversion input channel (29),

wherein the synchronized cardioversion input signal is one of an external ECG waveform (50) or an external synchronized pulse (51) indicative of a detection by the external ECG monitor (40) of at least one QRS complex of the external ECG waveform (50); and

the defibrillator (20) conditionally delivering a defibrillation shock synchronized with the synchronized cardioversion input signal in response to the defibrillator (20) receiving the synchronized cardioversion input signal.

14. The method of claim 13, further comprising:

the defibrillator (20) detecting the synchronized cardioversion input signal is the external ECG waveform (50) in response to the synchronized cardioversion input signal being nonequivalent to a pulse profile (32); and

the defibrillator (20) detecting the synchronized cardioversion input signal is the external synchronized pulse (51) in response to the synchronized cardioversion input signal being equivalent to the pulse profile (32).

15. The method of claim 14, further comprising:

the defibrillator (20) detecting the at least one QRS complex of the external ECG waveform (50),

wherein the defibrillator (20) delivers the defibrillation shock synchronized with the synchronized cardioversion input signal in response to detecting the at least one QRS complex of the external ECG waveform (50).

16. The method of claim 14, further comprising:

the defibrillator (20) detecting the at least one QRS complex of the external ECG waveform (50);

the defibrillator (20) detecting the at least one QRS complex of an internal ECG waveform (30); and

the defibrillator (20) measuring a time delay between the internal ECG waveform (30) and the external ECG waveform (50),

wherein the defibrillator (20) delivers the defibrillation shock synchronized with the synchronized cardioversion input signal in response to the measured time delay between the internal ECG waveform (30) and the external ECG waveform (50) being less than a baseline time delay.

17. The method of claim 14, further comprising:

the defibrillator (20) detecting the at least one QRS complex of the external ECG waveform (50);

the defibrillator (20) detecting the at least one QRS complex of an internal ECG waveform (30); and

the defibrillator (20) measuring a time delay between the internal ECG waveform (30) and the external ECG waveform (50),

wherein the defibrillator (20) executes at least one of a warning or a prohibition of a delivery of the defibrillation shock synchronized with the synchronized cardioversion input signal in response to the measured time delay between the internal ECG waveform (30) and the external ECG waveform (50) being greater than a baseline time delay.

18. The method of claim 14, wherein the defibrillator (20) delivers the defibrillation shock synchronized with the synchronized cardioversion input signal in response to detecting the synchronized cardioversion input signal is the external synchronized pulse (51).

19. The method of claim 14, further comprising:

the defibrillator (20) detecting the at least one QRS complex of an internal ECG waveform (30); and

the defibrillator (20) measuring a time delay between the internal ECG waveform (30) and the synchronized pulse (51),

wherein the defibrillator (20) delivers the defibrillation shock synchronized with the synchronized cardioversion input signal in response to the measured time delay between the internal ECG waveform (30) and the synchronized pulse (51) being less than a baseline time delay.

20. The method of claim 14, further comprising:

the defibrillator (20) detecting the at least one QRS complex of an internal ECG waveform; and

the defibrillator (20) measuring a time delay between the internal ECG waveform (30) and the synchronized pulse (51),

wherein the defibrillator (20) executes at least one of a warning or a prohibition a delivery of the defibrillation shock synchronized with the synchronized cardioversion input signal in response to the measured time delay between the internal ECG waveform (30) and the synchronized pulse (51) being greater than a baseline time delay.

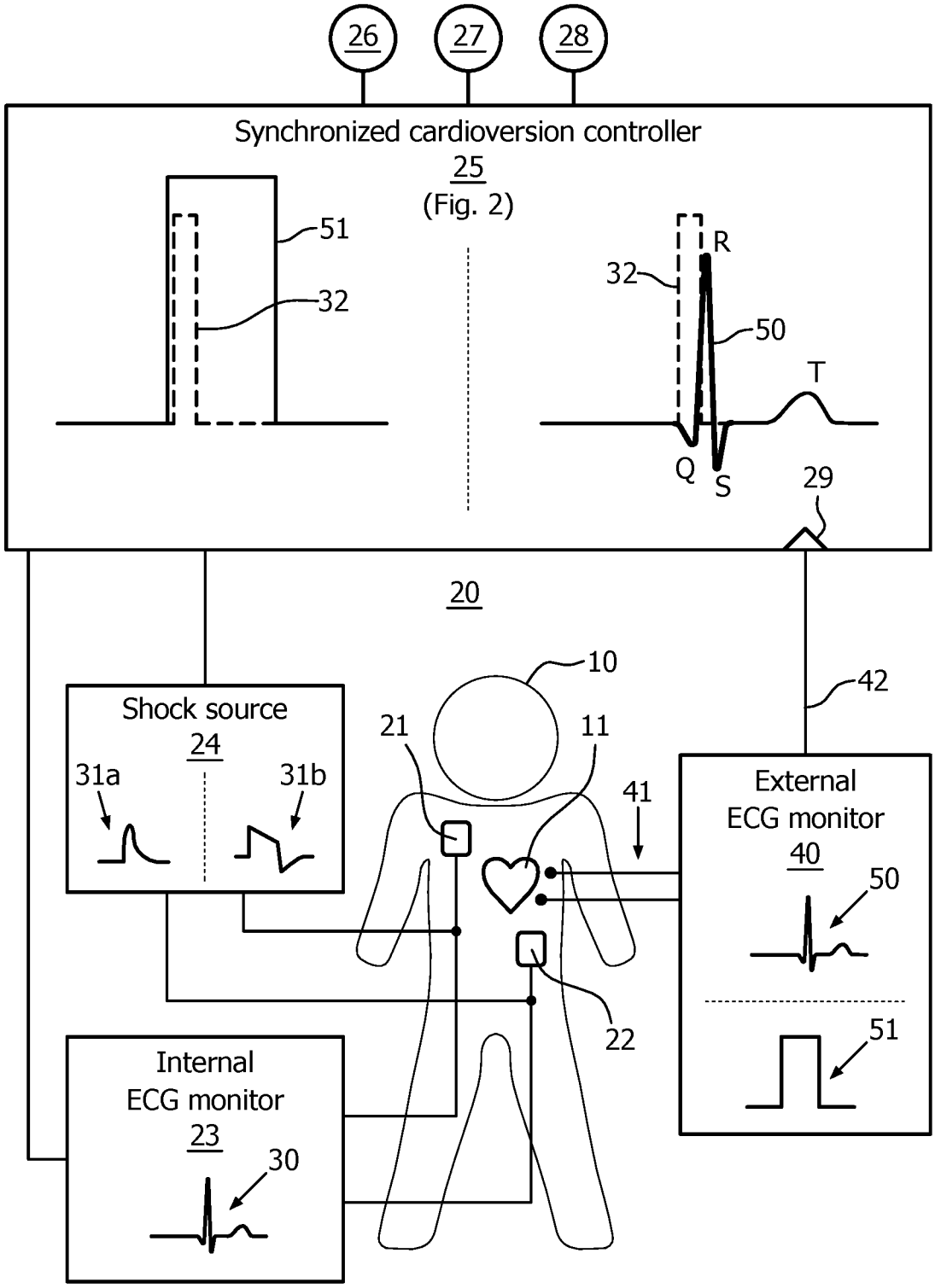
26
27
28
Synchronized cardioversion controller
25
(Fig. 2)
51
32
R
32
50
T
Q
S
29
20
10
42
Shock source
24
31a
31b
21
11
41
External
ECG monitor
40
50
51
22
Internal
ECG monitor
23
30

FIG. 1

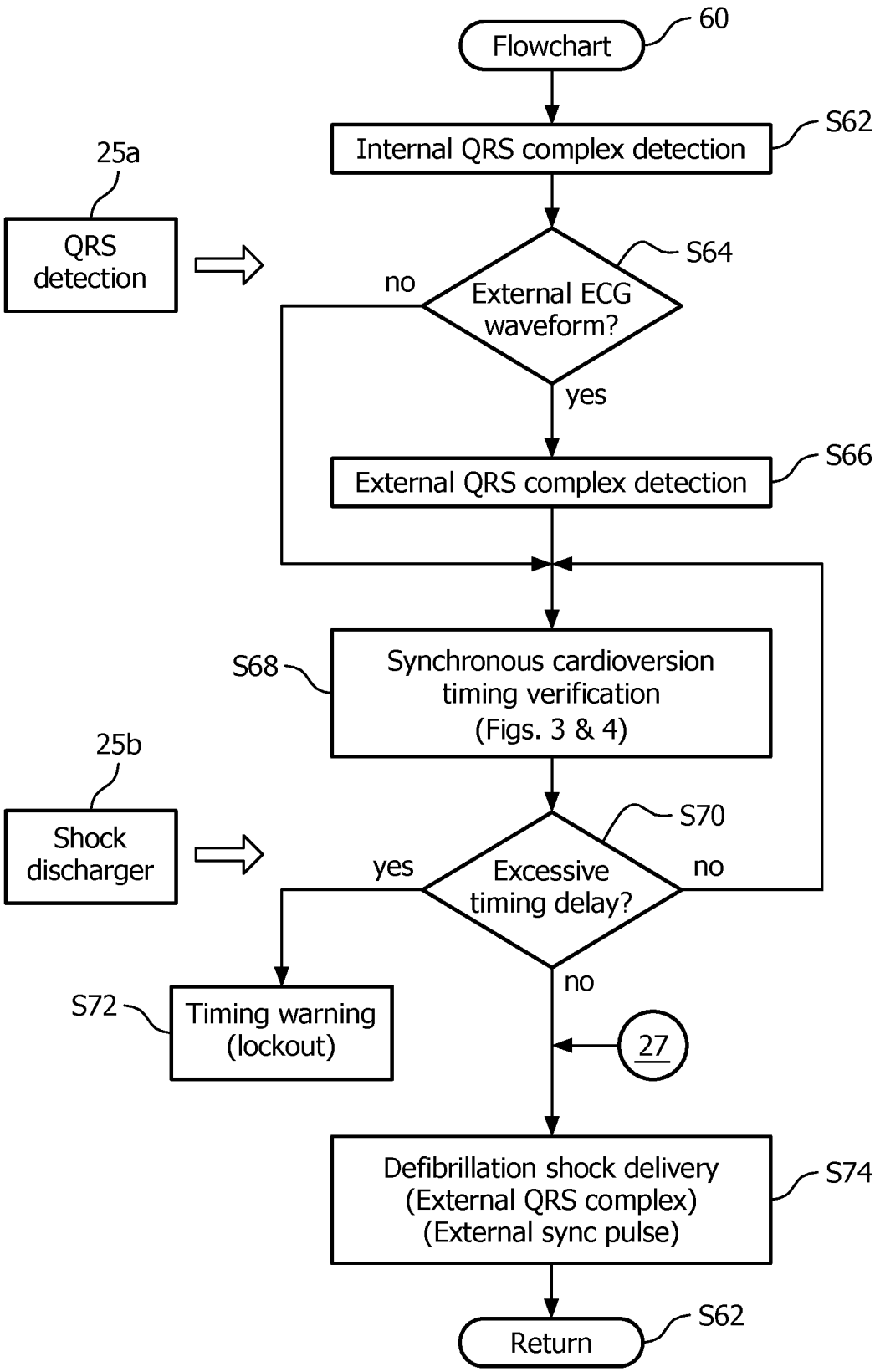
Flowchart
60
Internal QRS complex detection
S62
25a
QRS detection
S64
no
External ECG waveform?
yes
External QRS complex detection
S66
S68
Synchronous cardioversion timing verification (Figs. 3 & 4)
25b
Shock discharger
S70
yes
Excessive timing delay?
no
no
S72
Timing warning (lockout)
27
Defibrillation shock delivery (External QRS complex) (External sync pulse)
S74
Return
S62

FIG. 2

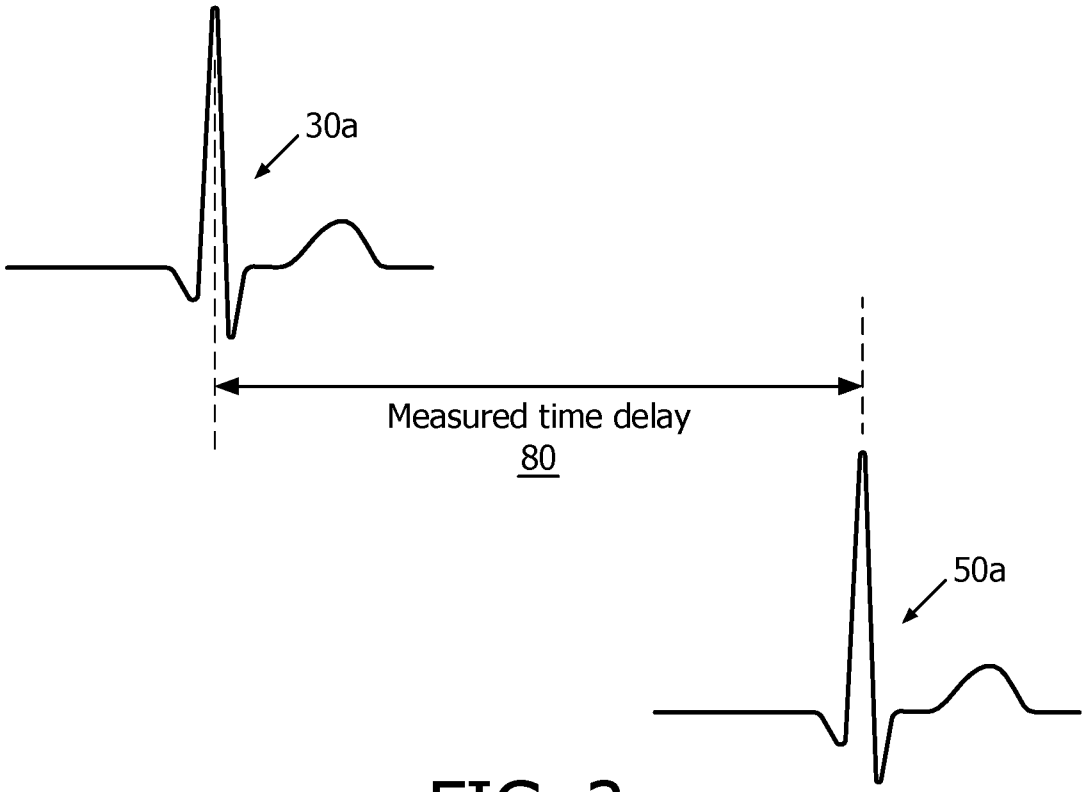


FIG. 3

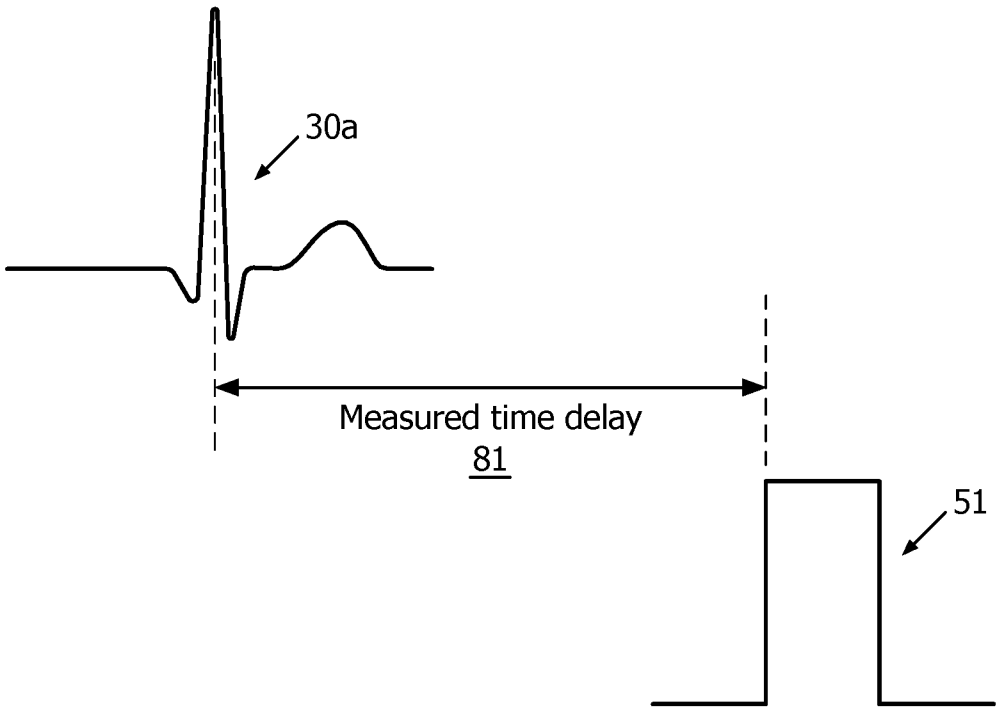


FIG. 4

# INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2014/062091

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/39 A61B5/0245
ADD.

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)
A61N A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 7 085 601 B1 (BARDY GUST H [US] ET AL)<br>1 August 2006 (2006-08-01) | 1-3,6,9,<br>10 |
| A | abstract; figures 3, 4,7<br>column 3, line 12 - column 9, line 42 | 4,5,7,8,<br>11,12 |
| | --- | |
| A | US 2007/255150 A1 (BRODNICK DONALD E [US])<br>1 November 2007 (2007-11-01)<br>abstract; figures 1, 5-13<br>paragraphs [0002] - [0010], [0026] -<br>[0033], [0036] - [0080] | 1-12 |
| | --- | |
| A | US 3 952 750 A (MIROWSKI MIECZYSLAW ET AL)<br>27 April 1976 (1976-04-27)<br>abstract; figures 1-3<br>column 1, line 40 - column 6, line 62 | 1-12 |
| | --- | |

☐ Further documents are listed in the continuation of Box C.

☒ See patent family 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 application or patent 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

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 30 September 2014 | 10/10/2014 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Mendelevitch, L |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2014/062091

**Box No. II Observations where certain claims were found unsearchable (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. [X] Claims Nos.: 13-20
because they relate to subject matter not required to be searched by this Authority, namely:

The subject-matter of claims 13 to 20 concerns a method for treatment of the human or animal body by therapy. Particularly, the step of delivering a defibrillation shock constitutes a treatment of the heart. According to the PCT no search is required for such subject-matter (Rule 39.1(iv) PCT).

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 No. 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 fees, this Authority did not invite payment of additional fees.

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 and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2014/062091

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 7085601 B1 | 01-08-2006 | NONE | |
| US 2007255150 A1 | 01-11-2007 | NONE | |
| US 3952750 A | 27-04-1976 | DE 2612768 A1 | 06-10-1977 |
| | | GB 1535829 A | 13-12-1978 |
| | | US 3952750 A | 27-04-1976 |