Oct. 26, 1971 M. MIROWSKI ET AL 3,614,955

STANDBY DEFIBRILLATOR AND METHOD OF OPERATION

Filed Feb. 9, 1970

2 Sheets-Sheet 1

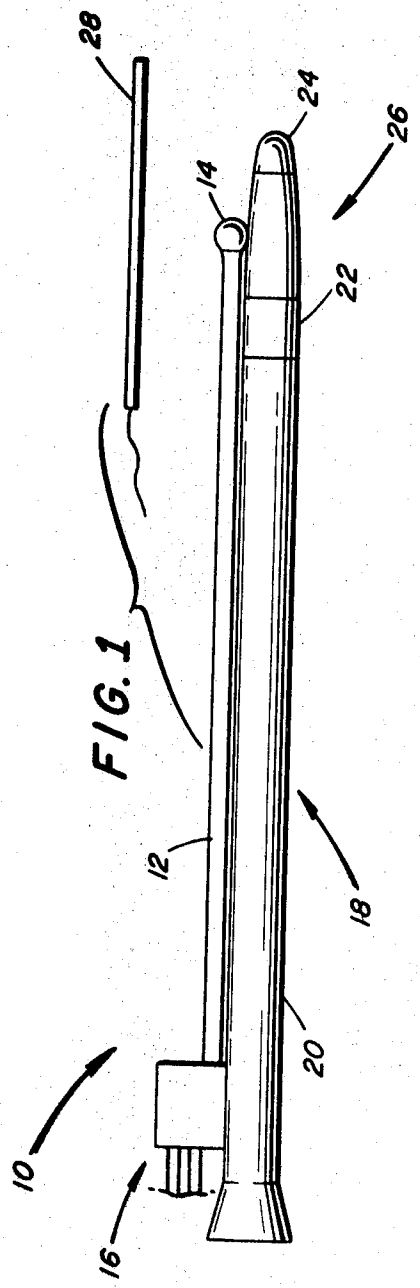

FIG. 1

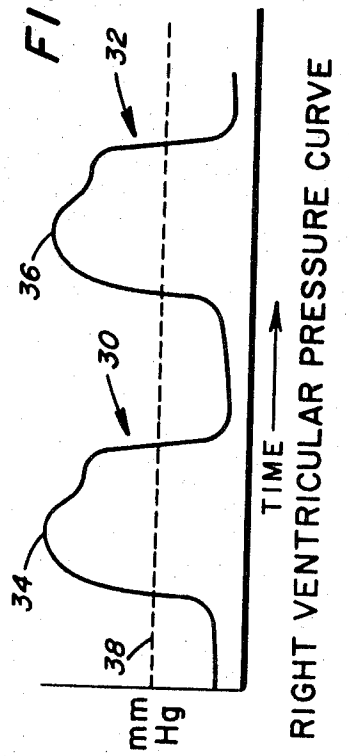

FIG. 2

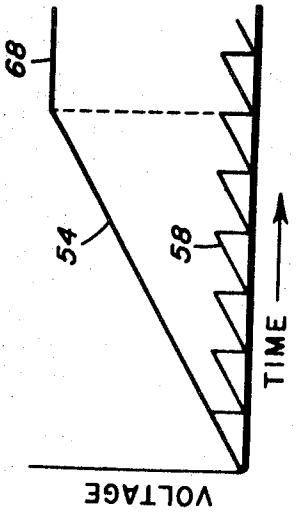

FIG. 4

INVENTOR
MIECZYSLAW MIROWSKI

BY Fleit, Gipple & Jacobson
ATTORNEYS

Oct. 26, 1971 M. MIROWSKI ET AL 3,614,955

STANDBY DEFIBRILLATOR AND METHOD OF OPERATION

Filed Feb. 9, 1970 2 Sheets-Sheet 2

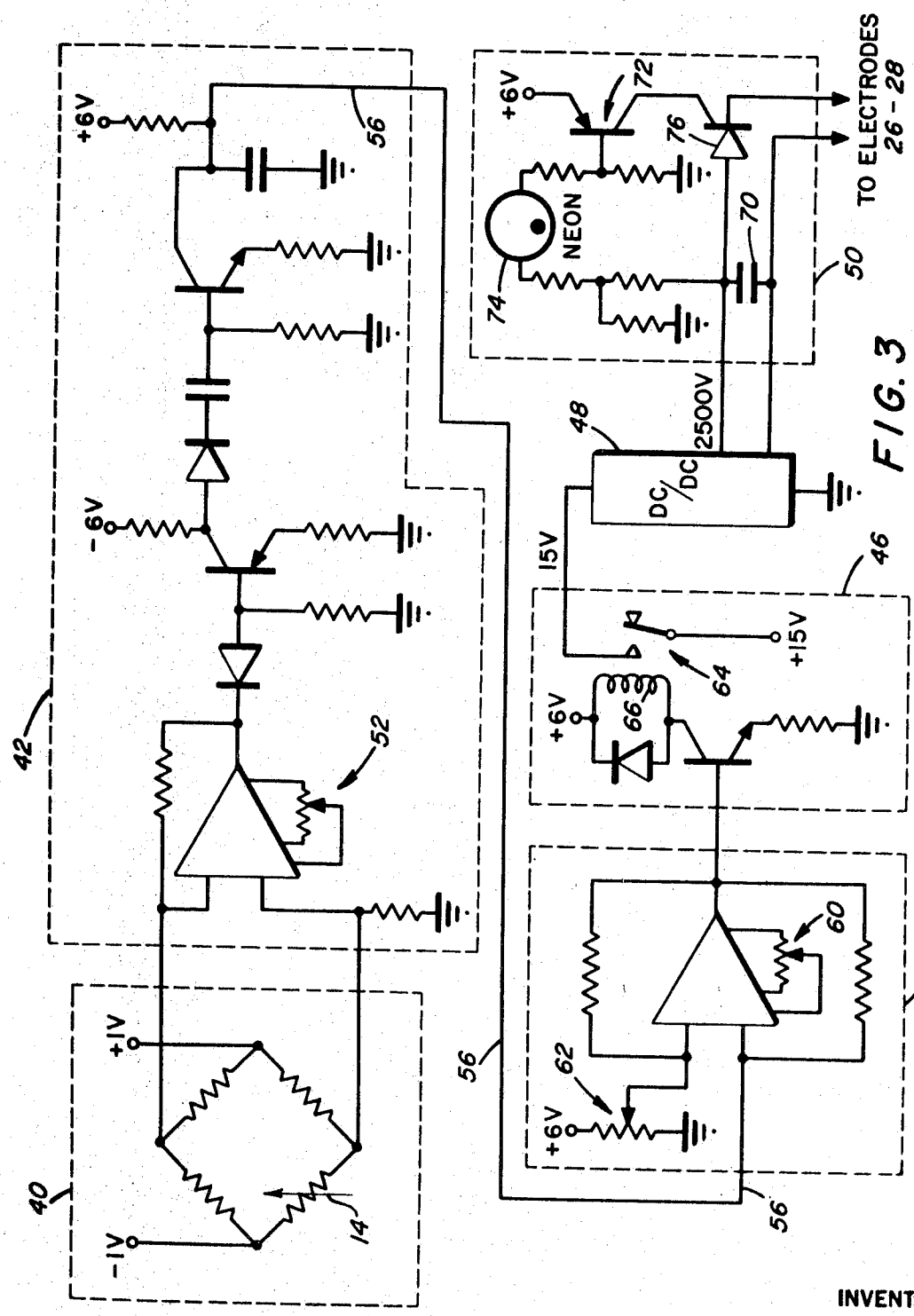

FIG. 3

INVENTOR
MIECZYSLAW MIROWSKI

BY Fleit, Gipple & Jacobson
ATTORNEYS

United States Patent Office 3,614,955
Patented Oct. 26, 1971

3,614,955

STANDBY DEFIBRILLATOR AND METHOD OF OPERATION

Mieczyslaw Mirowski, Baltimore, Md., assignor to Medtronic, Inc., Minneapolis, Minn.

Filed Feb. 9, 1970, Ser. No. 9,935
Int. Cl. A61n 1/34
U.S. Cl. 128—419 D 6 Claims

ABSTRACT OF THE DISCLOSURE

A method and means for automatically defibrillating a malfunctioning heart. With the present invention, the heart function is continuously monitored. When the function becomes abnormal, the malfunctioning heart is automatically shocked by a voltage of substantial size. If the heart does not return to its normal functions after a given interval, then it is again shocked. Normal heart activity ensures that the shocking mechanism remains inert.

BACKGROUND OF THE INVENTION

During the past several decades, coronary heart disease has come to occupy the first position among the causes of death in the developed areas of the world. In the United States, for example, this disease is responsible for over one-half million deaths yearly. And of this number, more than half occur suddenly, outside the hospital, and therefore before the patient is able to obtain the necessary medical assistance. Although the precise cause of sudden death in coronary heart disease has not yet been entirely clarified, the available evidence permits the medical field to ascribe death in the majority of these cases to grave disturbances in cardiac electrical activity resulting in ventricular fibrillation.

Recent experience has clearly demonstrated that ventricular fibrillation and its frequent precursor, ventricular tachycardia, are reversible phenomena when prompt defibrillation of the heart is instituted. Under such circumstances, cardiac function can frequently be restored to normal without the patient suffering from residual disability. Unfortunately, however, the state of the art makes defibrillation very much dependent upon a highly specialized medical environment, thus limiting such treatment to elaborately equipped modern hospitals.

At the present, therefore, a great need exists for a defibrillator which could be carried by those who are prone to having one of the many life threatening arrhythmias generally discussed above. Thus, in some patients having coronary heart disease, a fatal outcome from ventricular tachycardia or ventricular fibrillation could be avoided, even in the absence of immediate medical assistance. The first step, of course, is the detection of those prone to suffering from cardiac malfunctions leading to ventricular tachycardia or ventricular fibrillation.

While it is not possible to predict with unerring exactness which patient suffering from coronary heart disease will be the victim of sudden death, several high risk groups of patients can be recognized. For example, patients who have experienced myocardial infarction, even though they may be surviving in good health, run a substantial risk of dying suddenly, a risk several times greater than that associated with the general population. Further, if patients with myocardial infarction have a history of serious ventricular arrhythmias and/or of cardiac arrest, or if evidence of persistent myocardial irritability is present, it may be logically assumed that the risk of sudden death is increased substantially. Patients like those described above would greatly benefit if an automatic, standby or demand defibrillator were available.

Also, such an automatic defibrillator would be an asset to those hospital patients who have suffered myocardial infarction and who have been discharged from the well-equipped coronary care unit. Under such circumstances, the defibrillator could be implanted temporarily for the remainder of the expected hospital stay; or the defibrillator could be permanently implanted for use both in the hospital and after discharge. And another recognizable class of patients particularly in need of an automatic defibrillator is the class composed of those who have not shown prior histories of myocardial infarction but who show severe symptoms of coronary heart disease, such as ventricular arrhythmias resistant to medical treatment or angina pectoris.

From the brief discussion above, there should be little doubt that the possible applications for an automatic defibrillator are numerous. And, as previously noted, there is at present no known device which meets the need. It is toward filling this gap in medical instrumentation that the present invention is directed.

SUMMARY OF THE INVENTION

The present invention relates to a standby defibrillator, an electronic system which, after detecting one of the above-noted life threatening arrhythmias, automatically defibrillates the heart of the user. The system of the present invention may be installed in patients particularly prone to develop ventricular tachycardia and/or ventricular fibrillation, either on a temporary or a permanent basis. And, because of its small size, the device of the present invention may be entirely implanted under the skin of the patient, or alternatively, may be carried externally, save for the sensing electrode and one shock-applying electrode.

More particularly, the present invention relates to a device for reliably sensing the differences between a properly functioning heart and one which has suddenly developed ventricular fibrillation, and which then delivers a defibrillating shock to the heart in fibrillation. The device is adapted to continue delivering intermittent shocks to the heart in the event that the heart fails to return to its normal behavior pattern, and has the ability of automatically regaining sensing control over a functional heart thereby ensuring that further shocks are inhibited after successful defibrillation has taken place.

The standby defibrillator of the present invention has as its basic element, a capacitor capable of storing electrical energy in an amount sufficient to depolarize the human heart (on the order of 50 joules). Upon discharge of this capacitor, a shock is delivered to the heart through two stimulating electrodes. One of these electrodes is positioned within the right ventricle, thereby forming the distal tip of an intracardiac catheter. This electrode is introduced through a peripheral vein. The second stimulating electrode is positioned either on the surface of the chest, or is sutured under the skin of the anterior chest wall or directly to the ventricular myocardium.

The capacitor is associated with a sensing circuit connected to the proximal end of the intracardiac catheter and is adapted to respond to a signal recorded at the distal end of the catheter. The signal sensed by the catheter must, of course, be inherently related to some distinctive characteristic of ventricular tachycardia or ventricular fibrillation; and in a specific embodiment of the present invention, the pressure in the right ventricle is sensed. When this pressure falls below a given value, on the order of 10 to 15 mm. Hg, the heart is malfunctioning and, therefore, the capacitor is discharged into the heart.

Between the sensing circuit and the capacitor, means are provided for delaying the repetition of depolarizing discharges for a preset period of time (on the order of 20 to 30 seconds). This delay is essential to give the heart

the opportunity to convert spontaneously to a normal cardiac rhythm, and also to ensure that the abnormal heart conditions are, in fact, critical. Only in the absence of a successful conversion is a subsequent shock delivered to the heart. In a particular embodiment of the present invention, the time delay is brought about with the aid of a sawtooth generator, a relay and the charge time of the storage capacitor.

Accordingly, it is the main object of the present invention to provide a compact and automatic standby defibrillator which lies dormant during normal heart activity but which applies a shock to the heart when the heart functions become abnormal.

It is another object of the present invention to provide a standby defibrillator which reliably senses the difference between a normally functioning heart and one that has suddenly developed abnormal function, and which then automatically delivers a defibrillating shock to the heart.

It is a further object of the present invention to provide a standby defibrillator which is capable of delivering multiple shocks in the event that the heart is not successfully cardioverted by the initial shock.

It is yet a further object of the invention to provide a standby defibrillator which automatically regains sensing control over a functioning heart, thereby inhibiting further shocks after successful defibrillation.

It is still another object of the invention to provide a device employing a heart-implanted catheter which may sense both for defibrillation and for pacing the heart if required.

It is still another object of the present invention to provide a standby defibrillator which is extremely compact and which is therefore totally implantable in the body of a patient.

It is still another object of the invention to provide a method of operating a standby defibrillator.

These and other objects of the invention, as well as many of the attendant advantages thereof, will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the combination sensing probe and shock-applying probe forming a part of the present invention;

FIG. 2 illustrates a typical pressure curve for the right ventricle of a normally functioning heart;

FIG. 3 is a circuit schematic of the electronics comprising the standby defibrillator of the present invention; and

FIG. 4 is a graph of voltage versus time illustrating the operation of the sawtooth generator forming a part of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

With reference first to FIG. 1, the sensing and shock delivering probes will be described. The sensing probe is shown generally at **10** and comprises a main body portion **12** and a pressure sensitive bulb **14**. Electrical connections to the bulb **14** are made at junction box **16**. One of the shock delivering probes is shown generally at **18** and comprises a main body portion **20**, a first ring electrode **22** and a second ring electrode **24**. As will be explained below, the electrodes **22** and **24** are short-circuited together during the operation of the device, forming a composite electrode shown at **26**. The main body **12** of the sensing probe **10** is in the shape of a flat ribbon, and the body of the bulb **14** is spherical. The shock delivering probe **18** is substantially cylindrical.

As noted previously, the combination sensing probe **10** and shock delivering probe **18** is, during operation, positioned in the right ventricle of the heart. These probes are introduced into the heart through a peripheral vein by means of surgery very similar to that involved in the implantation of a pacemaker probe.

The shock delivering electrodes are two in number. The first electrode is the composite electrode **26** and is carried by the shock delivering probe **18**. The second electrode is shown at **28** and, in the preferred embodiment of this invention, is a flat plate either placed on the surface of the chest, sutured under the skin of the anterior chest wall or applied directly to the ventricular myocardium.

When the sensing probe **10** and the shock delivering probe **18** are inserted into the heart, the electrodes **22** and **24** are independent of one another. At this time, conventional pacemaking signals are applied between the electrodes **22** and **24**. Since the heart responds favorably to the pacemaking signals only if the probe **18** is properly positioned, this method is suitable for checking the position of the probes **10** and **18**. The probe location may, of course, be recognized by other methods such as, for example, fluoroscopy or pressure recordings. Once it is determined that the probes **10** and **18** are properly located, they are secured in place and the pacemaking electronics are disconnected. Then, the electrodes **22** and **24** are externally short-circuited together, and the electronic circuit associated with the standby defibrillator of the present invention is then connected to the probes **10** and **18** and the electrode **28**. If a pacemaking function is also to be carried out, the pacer electronics will remain connected and the step of shorting together the electrodes **22** and **24** will be eliminated.

With reference now to FIG. 2, there is illustrated a right ventricular pressure curve for a normally functioning heart. Pulses **30** and **32** are illustrated but, as is well known, these pulses repeat at the rate of approximately 60 to 70 per minute in a normally functioning heart. FIG. 2 clearly shows that each pulse has a peak and that these peaks rise above a preset pressure indicated by the dotted line **38**. This dotted line corresponds to the threshold between a healthy heart and one which is in need of defibrillation. When the height of the peaks **34** and **36** fall below the pressure indicated by line **38**, the malfunction is sensed by probe **10** which, as will be described immediately below, initiates the defibrillation of the heart.

With reference then to FIG. 3, the electronics associated with the standby defibrillator will be described. The electronic circuitry of FIG. 3 may conveniently be broken down into several component parts. The first part is a pressure transducer shown at **40**, this pressure transducer being directly associated with the pressure sensing probe **10** shown in FIG. 1. The next state of the electronics is an amplifier shown at **42** and adapted to amplify the signals received from the pressure transducer **40**. The amplified signal from the amplifier **42** is then passed to a sawtooth generator shown at **44**, which generator, in turn feeds its output signal to the base of a transistor associated with the relay stage shown at **46**. The relay **46** is normally in its open state condition but, when it is closed, a DC signal is impressed upon a DC/DC converter stage **48**. The DC/DC converter **48** boosts the input voltage from approximately 15 volts to approximately 2,500 volts. The 2,500 volt DC signal from the converter **48** is then fed to a storage capacitor **70** which is associated with a firing circuit, the entire combination shown at **50**. When the firing circuit **50** allows the capacitor **70** to discharge, the 2,500-volt signal is applied to the electrodes **26** and **28** illustrated in FIG. 1. Therefore, when the pressure sensing probe **10** recognizes a malfunction in the heart, the capacitor, after a predetermined time delay, shocks the heart with approximately 2,500 volts. This voltage corresponds to approximately 50 joules of power, enough power to cause most hearts to defibrillate.

Still referring to FIG. 3, but in greater detail, the circuitry associated with the present invention functions as follows. The pressure transducer **40** takes the form of a resistive bridge, one resistor of which is defined by the pressure sensor **14** on the tip of the probe **10**. The remaining legs in the bridge are defined by resistors housed in

the junction box **16** shown in FIG. 1. The pressure transducer **40** is arranged so that the pressure sensed by element **14** is converted to an electrical signal, the amplitude of which is directly proportional to the pressure sensed by the element **14**.

The output from the pressure transducer **40** is fed to a conventional amplifier **42** which amplifies the received pulses and which then feeds these amplified pulses to the sawtooth generator **44**. The trimming potentiometer **52** seems to balance the inputs to the associated amplifier.

With reference now to FIGS. 2 through 4, the operation of the sawtooth generator **44** will be described. The sawtooth generator **44**, if unaffected by the external environment, will have an output curve such as that shown at **54** in FIG. 4. However, if a signal is fed to the sawtooth generator, via lead **56**, and if the signal is at least of a predeterminded amplitude, then the output voltage of the generator will immediately drop to zero and then again begin to climb. Therefore, if the sawtooth generator receives repetitious pulses of at least the predetermined voltage, then its output will be similar to that of curve **58** shown in FIG. 4.

If the heart functions sensed by the pressure transducer **40** are normal, following the curve shown in FIG. 2, then the amplified signal corresponding to a pulse in the right ventricular pressure will cause the output of the sawtooth generator **44** to drop to zero. The threshold signal reaching the generator via lead **56**, can be adjusted by adjusting the amplification factor of the signal amplifier **42**. This threshold is adjusted so that the generator **44** activates the relay **64** only after approximately six seconds of heart malfunction. If, then, the ventricular pressure falls lower than that value indicated by the dotted line **38**, and so remains for the preset time interval, the amplified voltage reaching the generator **44**, via lead **56**, will be insufficient to cause the generator output to drop to zero. Rather, the generator output will follow the curve shown at **54** in FIG. 4. Trimming potentiometer **60** is provided to balance the inputs to the associated amplifier.

The output from the sawtooth generator **44** is fed to the relay circuit **46**. The relay contacts shown generally at **64** are initially set in the open-circuit condition, thereby isolating the 15-volt source from the DC/DC converter **48**. Further, the relay **64** is set to close only after the current passing through coil **66** reaches a predetermined value. With reference to FIG. 4, the voltage output of the sawtooth generator **44** must be at the level **68** before the current in the coil **66** is sufficient to switch the relay **64** into its closed-circuit state.

When the relay **64** closes, then the 15-volt source is connected directly to the DC/DC converter **48**. From FIGS. 2 through 4, it should be evident that approximately six seconds must elapse, with the heart continuously malfunctioning, before the relay **64** switches from its open-circuit mode to its closed-circuit mode. This will be apparent when one realizes that each "tooth" of the curve **58** corresponds to one peak of the right ventricular pressure curve and, as noted above, the peaks of the pressure curve repeat at approximately 60 to 70 per minute. Therefore, the heart pressure must be below the threshold level for approximately six seconds before input voltage is fed to the DC/DC converter **48**. If the heart returns to its normal function at any time during that six seconds, then the sawtooth generator output response would drop to zero and the six second cycle would begin again.

With the relay **64** closed and a 15-volt DC signal being impressed upon the converter **48**, an output of 2,500 volts appears at the output terminals of the converter **48**. This voltage is fed directly to storage capacitor **70**. Simultaneously, the 2,500-volt signal is fed to a resistive chain and finally to the base of transistor **72** via a neon tube **74**. A silicon controlled rectifier (SCR) is triggered on when transistor **72** becomes conductive.

The operation of the firing circuit **50** is as follows: the 2,500-volt signal from the converter **48** is fed to the capacitor **70**. When the capacitor **70** is fully charged, the transistor **72** becomes conductive, due to the now-conducting neon tube **74**. The resistor chains and the tube **74** are interconnected in such a manner that when the voltage across the capacitor **70** reaches the full 2,500 volts, then the tube **74** becomes conductive. When the tube **74** conducts, so too does transistor **72** and, therefore, SCR **76**. Then, the full 2,500 volts pass through electrodes **26** and **28** thus shocking the heart with a voltage sufficient to cause defibrillation.

As above noted, it is important that a time period elapse between the detection of a heart malfunction and the delivery of the defibrillating shock to the heart. As also noted above, approximately six seconds of delay occur between the first detection of a malfunction and the closing of the relay **64**. There is an additional delay, on the order of fifteen seconds, which is brought about by the charge time of the capacitor **70**. That is, when the relay **64** closes, six seconds after the initial malfunction, the capacitor first begins to charge. The capacitor employed in the preferred embodiment charges in approximately fifteen seconds. Therefore, approximately twenty-one seconds elapse between the initial sensing of heart malfunction and the discharge of the capacitor into the heart. Naturally by varying the rise time of the sawtooth generator and the charge time of the capacitor, the twenty-one seconds may be enlarged or contracted as desired. And, as mentioned above, if at any time during the delay period the heart returns to normal, then the delay period automatically begins again.

Above, a specific embodiment of the present invention has been described. It should be understood, however, that this description is given for illustrative purposes only and that many alterations and modifications may be practiced without departing from the spirit and scope of the invention. Just as a few examples, it should be understood that while in the specific embodiment of the present invention, the pressure in the right ventricle is sensed as an indication of heart malfunction, other sensing arrangements may be practiced. Further, a single SCR is used as a triggering device. It is possible to substitute this device for a plurality of SCR units or, alternatively, with a vacuum relay. Still further, while the above description shows a single storage capacitor, a series of capacitors could be employed. It is, therefore, the intent that the present invention not be limited to the above but be limited only as defined in the appended claims.

What is claimed is:

1. A device for automatically cardioverting a malfunctioning heart, the device comprising: means for continually sensing the function of a heart; means associated with said sensing means for discriminating between normal heart function and abnormal heart function; means for storing electrical energy for cardioverting a malfunctioning heart; electrode means associated with said storage means for connecting the storage means directly to the heart; at least one of said electrode means adapted to be positioned within the heart; and means for automatically switching said storage means into a discharge state in response to an abnormal condition indication from said discriminating means whereby the stored energy is applied directly to the heart through said electrode means.

2. The device as set forth in claim **1**, and further comprising: delay means for ensuring that a time delay exists between the sensing of the initial heart malfunction and the discharge of said storage means into the heart.

3. The device as set forth in claim **1**, and further comprising: means for inhibiting the discharge of said storage means under conditions of normal heart activity.

4. The method of automatically sensing and cardioverting a malfunctioning heart, the method comprising the steps of: continually sensing the function of the heart; discriminating between normal heart function and abnormal heart function; automatically starting a cycle for shocking the heart, in response to the sensing of abnormal

heart function, shocking the heart to cause cardioversion; and positively inhibiting the heart shocking cycle under conditions of normal heart function.

5. A device for automatically cardioverting a malfunctioning heart, the device comprising: means for continually sensing the function of a heart; means associated with said sensing means for discriminating between normal heart function and abnormal heart function; means for storing electrical energy for cardioverting a malfunctioning heart; electrode means associated with said storage means for connecting the storage means directly to the heart; means for automatically switching said storage means into a discharge state whereby the stored energy is applied directly to the heart through said electrode means; delay means for ensuring that a time delay exists between the sensing of the initial heart malfunction and the discharge of said storage means into the heart; and means

for inhibiting the discharge of said storage means whenever conditions of normal heart activity are sensed.

6. The device as recited in claim 5 wherein at least one of said electrode means is adapted to be positioned within the heart.

References Cited

UNITED STATES PATENTS

3,135,264	6/1964	Tischler et al.	128—419 D
3,236,239	2/1966	Berkovits	128—419 D
3,358,690	12/1967	Cohen	128—419 D
3,481,341	12/1969	Siedband	128—419 D

WILLIAM E. KAMM, Primary Examiner

U.S. Cl. X.R.

128—2.05 P, 2.06 A