(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 646 111 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
24.10.2018 Bulletin 2018/43

(21) Application number: **11787911.4**

(22) Date of filing: **25.11.2011**

(51) Int Cl.:
A61B 5/00 *(2006.01)* ***A61B 5/0452*** *(2006.01)*
A61B 5/053 *(2006.01)* ***A61N 1/39*** *(2006.01)*

(86) International application number:
PCT/EP2011/071069

(87) International publication number:
WO 2012/072518 (07.06.2012 Gazette 2012/23)

(54) AN EXTERNAL DEFIBRILLATOR

EXTERNER DEFIBRILLATOR

DÉFIBRILLATEUR EXTERNE

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **29.11.2010 IE 20100746**

(43) Date of publication of application:
09.10.2013 Bulletin 2013/41

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(56) References cited:
EP-A1- 2 172 245
WO-A1-2009/109595
US-A- 4 619 265
US-A- 5 247 939
US-A1- 2006 025 825
US-A1- 2011 224 746
US-B1- 6 287 328

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Description

[0001] This invention relates to an external defibrillator.

[0002] External automated defibrillators are normally connected to a patient via two electrodes. An electrocardiogram (ECG) and the patient's transthoracic impedance (ICG) are continuously recorded by the defibrillator and analysed using a diagnostic algorithm in order to detect a shockable rhythm, e.g. ventricular fibrillation (VF). If such a rhythm is found, the defibrillator prompts an audible/visible message to the operator (rescuer) to activate the defibrillator to deliver a therapeutic shock which may allow the patient to regain a perfused rhythm.

[0003] The use of a defibrillator involves a stressful time for the operator where the patient requires a fast and adequate treatment. The patient could be moved during preparation for CPR or checking for vital signs, etc., or the electrodes could be inadvertently touched after their application to the patient and while the ECG is being analysed. Any of these actions can introduce noise into the ECG and ICG signals being acquired by the defibrillator through the attached electrodes. This signal noise can mislead the diagnostic algorithm and cause it to generate a false determination of a shockable rhythm. This represents a risk to the patient when a non-shockable rhythm is wrongly classified as a shockable one and a risk to the operator when a shock is delivered while manipulating the patient.

[0004] US 5,247,939 discloses a defibrillator/monitor employing a motion detection circuit and control and processing circuit that cooperatively detect motion at a patient-electrode interface. In particular, an impedance measurement circuit produces an output indicative of the impedance of the interface, which output is then fed into a differentiator to produce an output that is proportional to the derivative of the impedance signal. The magnitude of the differentiated output is proportional to the motion detected, at least over short intervals. The motion detection routine includes subroutines that compare the impedance against distinct upper and lower limits and then monitor the time at which the signal is above and below the limits. Basically, motion is indicated if the signal undergoes relatively large variations for a short time, or smaller variations for a longer time. A third motion clear subroutine is used to determine when motion is no longer detected. Finally, a similar scheme is employed to quickly restore the various filter elements after saturation.

[0005] It is therefore desirable that lay responders using public access defibrillators are provided with more reliable and safer devices.

[0006] The present invention is defined by the appended claims. The examples, embodiments, or aspects of the present description that do not fall within the scope of said claims are merely provided for illustrative purposes and do not form part of the invention. Furthermore, any surgical, therapeutic, or diagnostic methods presented in the present description are provided for illustrative purposes only and do not form part of the present invention.

[0007] According to an aspect of the present invention, there is provided an external defibrillator as specified in Claim 1.

[0008] According to the invention there is provided an external defibrillator including patient electrodes for obtaining the patient's electrocardiogram (ECG) and for applying a shock to a patient, circuit means for analysing the patient's ECG using a diagnostic algorithm to detect if the patient's heart is in a shockable rhythm, and shock delivery circuitry which is enabled when a shockable rhythm is detected by the diagnostic algorithm, wherein the patient electrodes also allow obtaining a signal (Z) which is a measure of the patient's transthoracic impedance and the circuit means is responsive to Z to detect interference conditions likely to cause the diagnostic algorithm to generate a false detection of a shockable rhythm and, if such detection is made, to prevent detection of a shockable rhythm by the diagnostic algorithm, at least for a period of time.

[0009] In a preferred embodiment the circuit means detects said conditions by forming the first derivative dZ/dt of Z, deriving a quantity related to the energy of dZ/dt in a moving time window, and determining if said energy-related quantity exceeds a certain threshold level.

[0010] The present invention uses the patient's transthoracic impedance to detect when a faulty classification is likely to occur, since the impedance signal is more sensitive to interferences such as movement of the patient and touching electrodes by the operator than the ECG. Dramatic changes observed in the patient's impedance are strong indicators of interferences such as those mentioned above taking place.

[0011] An embodiment of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a block diagram of an automated external defibrillator embodying the invention.

Figure 2 is an impedance waveform illustrating the first derivative dZ/dt of the impedance signal Z during periods of no interference and interference respectively.

Figure 3 is a flow diagram of an algorithm to detect conditions likely to cause the diagnostic algorithm to generate a false detection of a shockable rhythm.

[0012] Referring to Figure 1, an automated external defibrillator comprises three main sections: 10, 12 and 14.

[0013] Section 10 is the main high voltage shock circuitry and comprises a bank of capacitors 16 which are charged up to a high voltage by a charging circuit 18, the charge being released as a bi-phasic high voltage shock through a pair of patient electrodes 20 by a bridge circuit

22. The charging of the capacitors 16 and the shape and duration of the bi-phasic shock waveform is controlled by a microprocessor 24, the actual shock being given by the user pressing a button (not shown) if the patient's condition is deemed "shockable" as determined by a diagnostic algorithm having the patient's ECG as input. The ECG is derived from the patient electrodes 20 in known manner, not shown. The process is prompted by voice messages and/or visual prompts output on visual/audio indicators 38 (the indicators are shown in section 12 for diagrammatic simplicity). The audio/visual output indicators 38 may comprise a loudspeaker and/or LED(s).

[0014] Section 12 measures the patient's transthoracic impedance using the same electrodes 20 as are used for applying the shock. A generator 26 produces a 30 kilohertz sinusoidal waveform at a constant current of 100 microamperes. This signal is applied across the electrodes 20. When the electrodes are attached to a patient, a voltage across the electrodes is generated which is superimposed on the 30kHz sinusoid. This voltage is a direct measurement of the transthoracic impedance of the patient. The voltage generated in response to the sinusoid is applied to a differential amplifier 28 which converts it from a differential signal to a single signal referenced to ground potential. The resultant waveform is passed through a low pass filter 30 which removes the original 30kHz signal leaving a signal Zo (static impedance) which is directly proportional to the patient impedance. The impedance signal Zo is used by the microprocessor 24 to set the bi-phasic pulse amplitude and width to ensure that the correct total energy (typically 150 Joules) is delivered to the patient.

[0015] The construction and operation of sections 10 and 12 of the AED are well-known, and it is not thought that further detail is necessary.

[0016] The purpose of section 14 is to provide further conditioning of the impedance signal Zo as input to an algorithm to detect circumstances likely to cause the main diagnostic algorithm to generate a false detection of a shockable rhythm. Section 14 is additional to the existing circuitry for the derivation of patient impedance in section 12.

[0017] In section 14 of the defibrillator the impedance signal Zo which is output from the low pass filter 30 is passed through a high pass filter 32 which removes the dc offset before removing higher frequency noise in the low pass filter 34. Finally the signal is scaled in an amplifier 36 incorporating digital gain control to a level appropriate for analogue-to-digital conversion by the microprocessor 24. The resultant filtered and amplified signal Z is digitally converted. In this embodiment the analog to digital sample rate is 170.66 samples per second. However, this is not a limitation for the detection of interference since adjustments in thresholds are possible to adapt to a different sample rate. The impedance signal Z is differentiated and the result dZ/dt is used in an algorithm, Figure 3, to detect interference conditions likely to cause the diagnostic algorithm to cause it to generate a false detection of a shockable rhythm.

[0018] First, however, reference is made to Figure 2 which shows a typical dZ/dt waveform during periods of no interference and interference respectively. On the left the signal has a relatively low energy, corresponding to a period when the patient and the electrodes are undisturbed. On the right, however, the signal becomes relatively much more energetic, corresponding to a period when the patient and/or electrodes are disturbed sufficiently to cause, or be likely to cause, the diagnostic algorithm to generate a false detection of a shockable rhythm. The algorithm of Figure 3 is therefore designed to detect periods when the energy of dZ/dt is above a threshold level likely to cause false detection. In particular, in the preferred embodiment, the algorithm detects disturbances likely to cause the diagnostic algorithm to generate a false detection of a shockable rhythm by forming the first derivative of Z (dZ/dt), deriving a signal related to the energy of dZ/dt in a moving time window, and determining if the energy signal exceeds a certain (empirically determined) threshold level.

[0019] Referring now to Figure 3, in respect of successive (preferably consecutive) digital values of Z input to the microprocessor 24 from the scaling amplifier 36 the algorithm performs the following steps for each such value:

a. At step 100 the signal Z is differentiated by software in the microprocessor 24 to obtain its first derivative dZ/dt.

b. Next, step 110, the amplitude of dZ/dt is calculated.

c. Next, step 120, if the amplitude of the signal dZ/dt is greater than a certain threshold a flag is set to 1, step 130, otherwise the flag is set to 0, step 140.

d. The flag values (0 or 1) are averaged over the last 0.75s, step 150. This is done by feeding a binary array of 128 elements (equivalent to 0.75s using a 170.66 sample rate). The oldest value in the array is substituted by the newest one, and the elements of the binary array are summed and divided by 128.

e. If this average is greater than 0.5, step 160, which means that most of the time dZ/dt has been higher than the threshold, the algorithm flags that it has detected interference or disturbance likely to cause the diagnostic algorithm to generate a false detection of a shockable rhythm (step 170). Otherwise no interference or disturbance is detected, step 180.

f. In the case of interference being found at step 170 the diagnostic algorithm in the defibrillator is prevented from detecting a shockable rhythm for a period of, in this embodiment, 4 seconds (step 190).

[0020] The process continues (step 200) until no more Z values are input, i.e. the Z signal is no longer present.

[0021] The threshold value used in step 120 of this embodiment was obtained empirically by analysing a large volume of patient data when interferences was documented. Additionally, the threshold value depends on the A-D sample rate, the gain from the amplifier 36, the resolution of Z, the length of the moving time window, the technique used for calculating dZ/dt, etc.

[0022] It will be evident that in this embodiment the average calculated at step 150 is a measure of the energy of the dZ/dt signal over the preceding 0.75s window. That is to say, the more often the amplitude of dZ/dt exceeds the threshold in the moving window, the greater the energy of the signal.

[0023] However, other methods of measuring the energy of the signal in a moving time window can be used in other embodiments of the invention. For example, the RMS value of the signal can be calculated, or peak-to-peak value.

[0024] The present invention is defined by the appended claims.

Claims

1. An external defibrillator including patient electrodes (20) for obtaining the patient's electrocardiogram (ECG) and for applying a shock to a patient, circuit means (12, 14) for analysing the patient's ECG using a diagnostic algorithm to detect if the patient's heart is in a shockable rhythm, and shock delivery circuitry (10) which is enabled when a shockable rhythm is detected by the diagnostic algorithm, wherein the patient electrodes (20) also allow obtaining a signal (Z) which is a measure of the patient's transthoracic impedance and the circuit means (12, 14) is configured to be responsive to Z to detect interference conditions likely to cause the diagnostic algorithm to generate a false detection of a shockable rhythm and, if such detection is made, to prevent detection of a shockable rhythm by the diagnostic algorithm, at least for a period of time, wherein the circuit means (12, 14) is configured to detect said interference conditions by using a microprocessor (24) of the circuit means for analog to digital converting of the signal Z, and in respect of successive digital values of Z, forming the first derivative (dZ/dt) of Z, deriving a quantity related to the energy of dZ/dt, determining if said energy-related quantity exceeds a certain threshold level, if said energy-related quantity exceeds the certain threshold level setting a value of a flag to 1, otherwise setting a value of the flag to 0, and in a moving time window averaging values of the flag over the time window and if an average of the flag values is greater than a further threshold level detecting interference conditions.

2. A defibrillator as claimed in claim 1, wherein the energy-related quantity is the amplitude of dZ/dt.

3. A defibrillator as claimed in claim 1 or claim 2, wherein the certain threshold level is obtained empirically from patient data when interference conditions are detected

4. A defibrillator as claimed in any preceding claim, wherein in the moving time window averaging values of the flag over the time window comprises feeding a most-recent flag value into a binary array of 128 elements of the flag values in the time window, substituting an oldest flag value with a newest flag value, summing the flag values and dividing the sum by the number of flag values in the array.

5. A defibrillator as claimed in any preceding claim, wherein the further threshold level is 0.5.

6. A defibrillator as claimed in any preceding claim, wherein the patient electrodes (20) comprise a single pair of electrodes for obtaining both the patient's ECG and transthoracic impedance.

Patentansprüche

1. Externer Defibrillator, der Folgendes umfasst: Patientenelektroden (20) zum Erhalten des Elektrokardiogramms (EKG) des Patienten und zum Anlegen eines Schocks an einen Patienten, Schaltungsmittel (12, 14) zum Analysieren des EKG des Patienten unter Verwendung eines Diagnosealgorithmus, um zu erkennen, ob sich das Herz des Patienten in einem schockfähigen Rhythmus befindet, und eine Schockabgabeschaltung (10), die aktiviert wird, wenn ein schockfähiger Rhythmus durch den Diagnosealgorithmus erkannt wird, wobei die Patientenelektroden (20) auch erlauben, ein Signal (Z) zu erhalten, das ein Maß für die transthorakale Impedanz des Patienten ist, und wobei das Schaltungsmittel (12, 14) für Folgendes konfiguriert ist: Reagieren auf Z, um Interferenzbedingungen zu erfassen, die dazu führen können, dass der Diagnosealgorithmus eine falsche Erfassung eines schockfähigen Rhythmus erzeugt, und wenn eine solche Erfassung vorgenommen wird, Verhindern des Erfassens eines schockfähigen Rhythmus durch den Diagnosealgorithmus mindestens für einen bestimmten Zeitraum, wobei das Schaltungsmittel (12, 14) für Folgendes konfiguriert ist: Erfassen der genannten Interferenzbedingungen unter Verwendung eines Mikroprozessors (24) des Schaltungsmittels zur Analog-Digital-Wandlung des Signals Z und bezüglich aufeinanderfolgender digitaler Werte von Z, Bilden der ersten Ableitung (dZ/dt) von Z, Ableiten einer Menge bezogen auf die Energie von dZ/dt, Bestimmen, ob die

genannte energiebezogene Menge einen bestimmten Schwellenwert übersteigt, wenn die genannte energiebezogene Menge den bestimmten Schwellenwert übersteigt, Einstellen eines Wertes eines Kennzeichens auf 1, andernfalls Einstellen eines Wertes des Kennzeichens auf 0, und in einem beweglichen Zeitfenster, Mitteln von Werten des Kennzeichens über das Zeitfenster, und wenn ein Mittelwert der Kennzeichenwerte größer ist als ein weiterer Schwellenwert, Erkennen der Interferenzbedingungen.

2. Defibrillator nach Anspruch 1, wobei die energiebezogene Größe die Amplitude von dZ/dt ist.

3. Defibrillator nach Anspruch 1 oder Anspruch 2, wobei der bestimmte Schwellenwert empirisch aus Patientendaten erhalten wird, wenn Interferenzbedingungen erfasst werden.

4. Defibrillator nach einem der vorhergehenden Ansprüche, wobei in dem Bewegungszeitfenster das Mittel von Werten des Kennzeichens über das Zeitfenster Folgendes umfasst: Einspeisen eines letzten Kennzeichenwertes in eine binäre Anordnung von 128 Elementen der Kennzeichenwerte in dem Zeitfenster, Ersetzen eines ältesten Kennzeichenwertes durch einen neuesten Kennzeichenwert, Summieren der Kennzeichenwerte und Dividieren der Summe durch die Anzahl der Kennzeichenwerte in der Anordnung.

5. Defibrillator nach einem der vorhergehenden Ansprüche, wobei der weitere Schwellenwert gleich 0,5 ist.

6. Defibrillator nach einem der vorhergehenden Ansprüche, wobei die Patientenelektroden (20) ein einzelnes Elektrodenpaar umfassen, um sowohl das EKG des Patienten als auch die transthorakale Impedanz zu erhalten.

Revendications

1. Défibrillateur externe incluant des électrodes de patient (20) pour l'obtention de l'électrocardiogramme du patient (ECG) et pour l'application d'un choc à un patient, un moyen formant circuit (12, 14) pour l'analyse de l'ECG du patient en utilisant un algorithme de diagnostic pour détecter si le coeur du patient est dans un rythme pouvant être choqué, et une circuiterie d'administration de choc (10) qui est activée quand un rythme pouvant être choqué est détecté par l'algorithme de diagnostic, dans lequel les électrodes de patient (20) permettent également l'obtention d'un signal (Z) qui est une mesure de l'impédance transthoracique du patient et le moyen formant circuit (12, 14) est configuré pour répondre à Z pour détecter des conditions d'interférence susceptibles d'amener l'algorithme d'interférence à générer une détection fausse d'un rythme pouvant être choqué et, si une telle détection est faite, pour empêcher la détection d'un rythme pouvant être choqué par l'algorithme de diagnostic, au moins pendant une période de temps, dans lequel le moyen formant circuit (12, 14) est configuré pour détecter lesdites conditions d'interférence à l'aide d'un microprocesseur (24) du moyen formant circuit pour la conversion analogique-numérique du signal Z, et par rapport aux valeurs numériques successives de Z, la formation du premier dérivé (dZ/dt) de Z, la dérivation d'une quantité liée à l'énergie de dZ/dt, le fait de déterminer si ladite quantité liée à l'énergie dépasse un certain niveau seuil, si ladite quantité liée à l'énergie dépasse le certain niveau seuil la fixation d'une valeur d'un indicateur à 1, autrement la fixation d'une valeur de l'indicateur à 0, et dans une fenêtre de temps variable la réalisation de la moyenne des valeurs de l'indicateur dans la fenêtre de temps et si une moyenne des valeurs d'indicateur est supérieure à un niveau seuil supplémentaire la détection de conditions d'interférence.

2. Défibrillateur selon la revendication 1, dans lequel la quantité liée à l'énergie est l'amplitude de dZ/dt.

3. Défibrillateur selon la revendication 1 ou la revendication 2, dans lequel le certain niveau seuil est obtenu de manière empirique à partir de données de patient quand des conditions d'interférence sont détectées.

4. Défibrillateur selon l'une quelconque des revendications précédentes, dans lequel dans la fenêtre de temps variable la réalisation de la moyenne des valeurs de l'indicateur dans la fenêtre de temps comprend l'entrée d'une valeur d'indicateur la plus récente dans une matrice binaire de 128 éléments des valeurs d'indicateur dans la fenêtre de temps, la substitution d'une valeur d'indicateur la plus ancienne par une valeur d'indicateur la plus récente, la réalisation de la somme des valeurs d'indicateur et la division de la somme par le nombre des valeurs d'indicateur dans la matrice.

5. Défibrillateur selon l'une quelconque des revendications précédentes, dans lequel le niveau seuil supplémentaire est 0,5.

6. Défibrillateur selon l'une quelconque des revendications précédentes, dans lequel les électrodes de patient (20) comprennent une seule paire d'électrodes pour obtenir l'ECG et l'impédance transthoracique du patient.

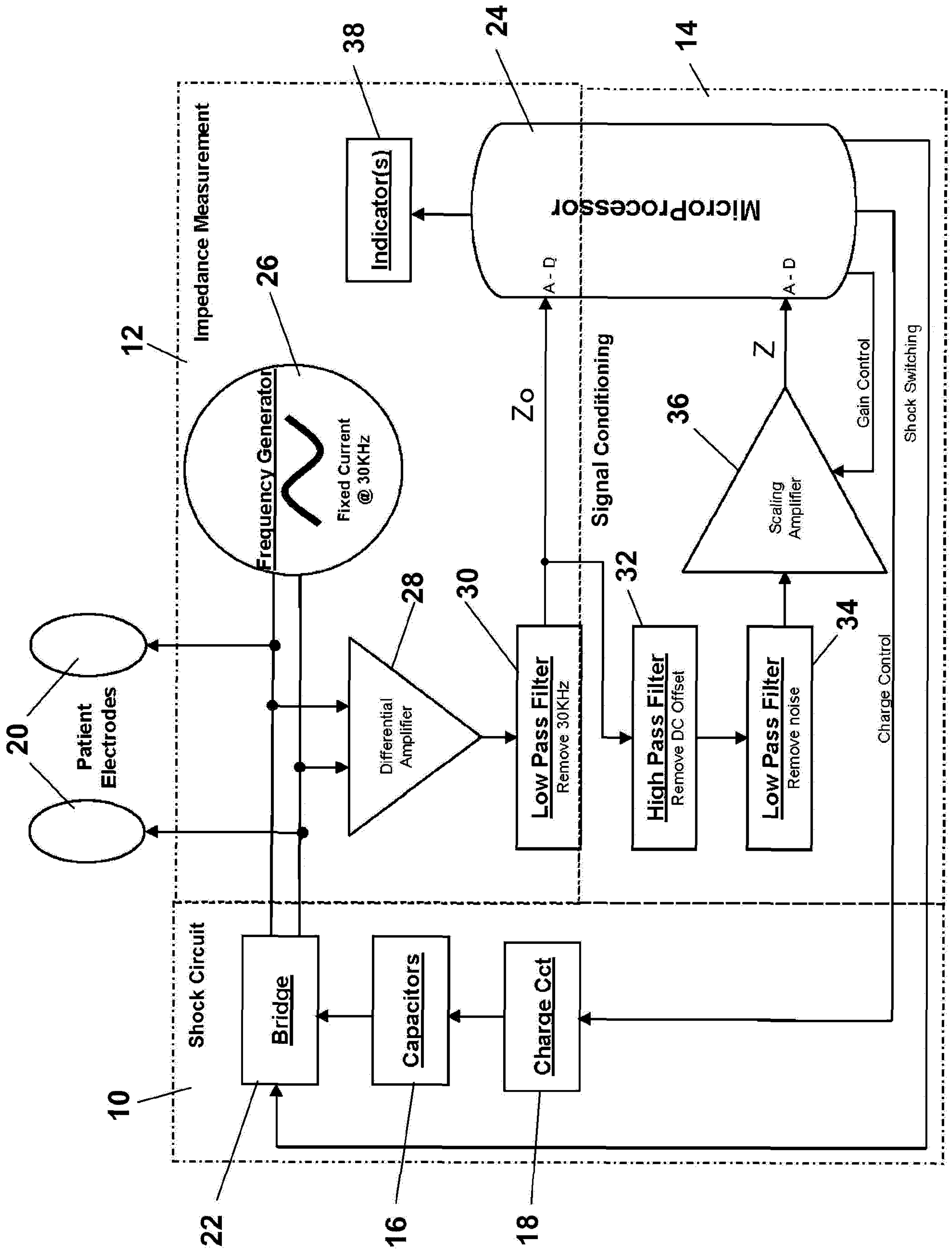
Shock Circuit
Bridge
Capacitors
Charge Cct
Impedance Measurement
Frequency Generator
Fixed Current
@ 30KHz
Patient
Electrodes
Differential
Amplifier
Low Pass Filter
Remove 30KHz
Signal Conditioning
High Pass Filter
Remove DC Offset
Low Pass Filter
Remove noise
Scaling
Amplifier
Zo
Z
Gain Control
Shock Switching
Charge Control
MicroProcessor
A - D
A - D
Indicator(s)
10
12
14
16
18
20
22
24
26
28
30
32
34
36
38

Figure 1

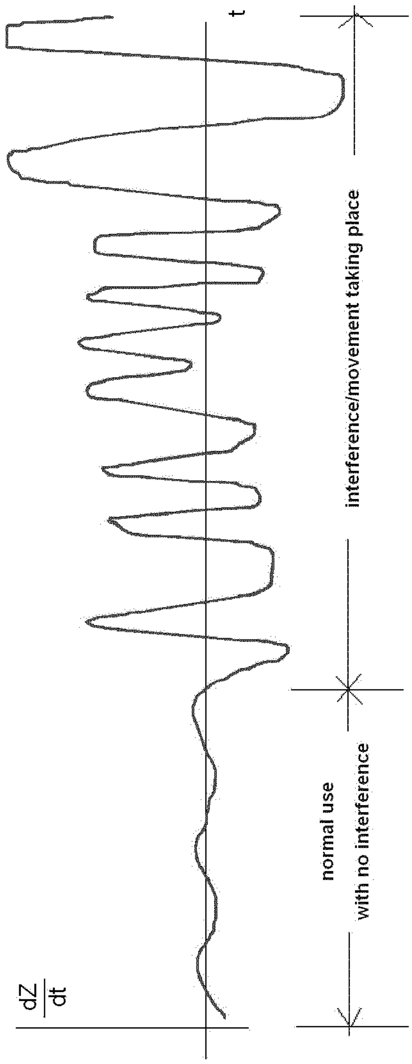
dZ/dt
t
normal use
with no interference
interference/movement taking place

Figure 2

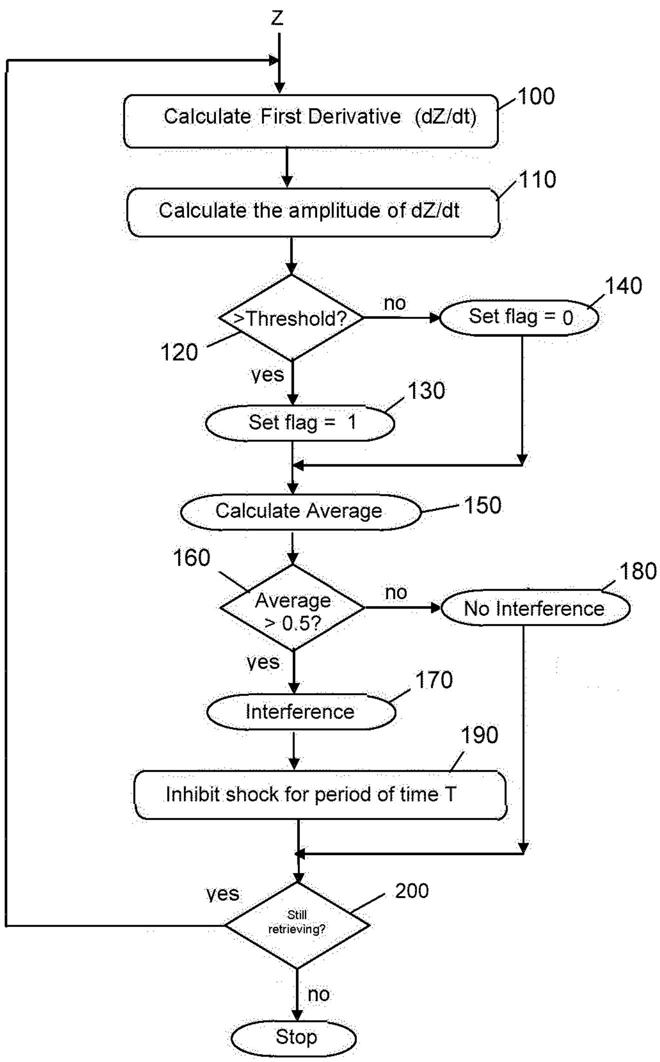
Z
Calculate First Derivative (dZ/dt)
100
Calculate the amplitude of dZ/dt
110
>Threshold?
120
no
Set flag = 0
140
yes
Set flag = 1
130
Calculate Average
150
160
Average > 0.5?
no
No Interference
180
yes
Interference
170
Inhibit shock for period of time T
190
yes
Still retrieving?
200
no
Stop

Figure 3

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 5247939 A **[0004]**

专利名称(译)	外部除颤器		
公开(公告)号	EP2646111B1	公开(公告)日	2018-10-24
申请号	EP2011787911	申请日	2011-11-25
申请(专利权)人(译)	HEARTSINE TECHNOLOGIES LIMITED		
当前申请(专利权)人(译)	HEARTSINE TECHNOLOGIES LIMITED		
[标]发明人	NAVARRO PAREDES CESAR OSWALDO ANDERSON JOHN MCCUNE		
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IPC分类号	A61B5/00 A61B5/0452 A61B5/053 A61N1/39		
CPC分类号	A61B5/0452 A61B5/0535 A61B5/7207 A61B5/721 A61B5/7239 A61N1/3931 A61N1/3918 A61N1/3925 A61N1/3987		
优先权	S20100746 2010-11-29 IE		
其他公开文献	EP2646111A1		
外部链接	Espacenet		

摘要(译)

外部除颤器包括患者电极（20），用于获得患者的心电图（ECG）并对患者施加电击。微处理器（24）使用诊断算法分析患者的ECG以检测患者的心脏是否处于可电击的节律，并且当诊断算法检测到可电击节律时启用电击传递电路（10）。患者电极还允许获得信号（Z），该信号是患者的经胸阻抗的量度，并且微处理器响应于Z以检测可能导致诊断算法产生可电击节律的错误检测的状况。如果进行了这样的检测，则微处理器至少在一段时间内防止通过诊断算法检测到可电击节律。