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Navarro-Paredes et al.

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(54) **EXTERNAL DEFIBRILLATOR**

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Related U.S. Application Data

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(30) **Foreign Application Priority Data**

Nov. 29, 2010 (IE) S2010/0746

(51) **Int. Cl.**

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A61N 1/39	(2006.01)
A61B 5/0452	(2006.01)
A61B 5/053	(2006.01)
A61B 5/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61N 1/3918*** (2013.01); ***A61B 5/0452*** (2013.01); ***A61B 5/0535*** (2013.01); ***A61B 5/721*** (2013.01); ***A61B 5/7207*** (2013.01); ***A61B 5/7239*** (2013.01); ***A61N 1/3925*** (2013.01); ***A61N 1/3931*** (2013.01); ***A61N 1/3987*** (2013.01)

(58) **Field of Classification Search**

CPC ... A61N 1/3918; A61N 1/3987; A61N 1/365; A61N 1/39; A61B 5/02

See application file for complete search history.

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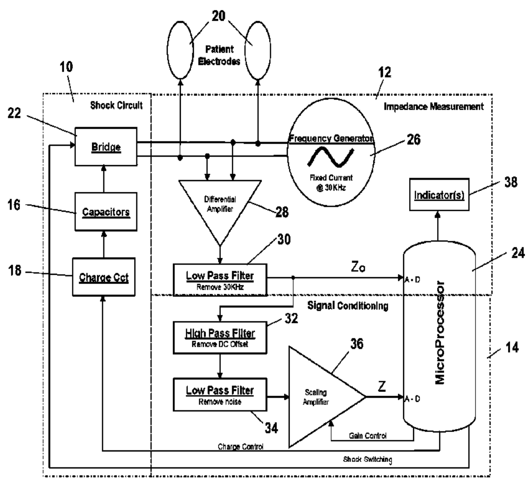
(57) **ABSTRACT**

An external defibrillator includes patient electrodes (**20**) for obtaining the patient's electrocardiogram (ECG) and for applying a shock to the patient. A microprocessor (**24**) analyses the patient's ECU using a diagnostic algorithm to detect if the patient's heart is in a shockable rhythm, and shock delivery circuitry (**10**) is enabled when a shockable rhythm is detected by the diagnostic algorithm. The patient electrodes also allow obtaining a signal (Z) which is a measure of the patient's transthoracic impedance and the microprocessor is responsive to Z to detect conditions likely to cause the diagnostic algorithm to generate a false detection of a shockable rhythm. If such detection is made, the microprocessor prevents detection of a shockable rhythm by the diagnostic algorithm, at least for a period of time.

18 Claims, 3 Drawing Sheets



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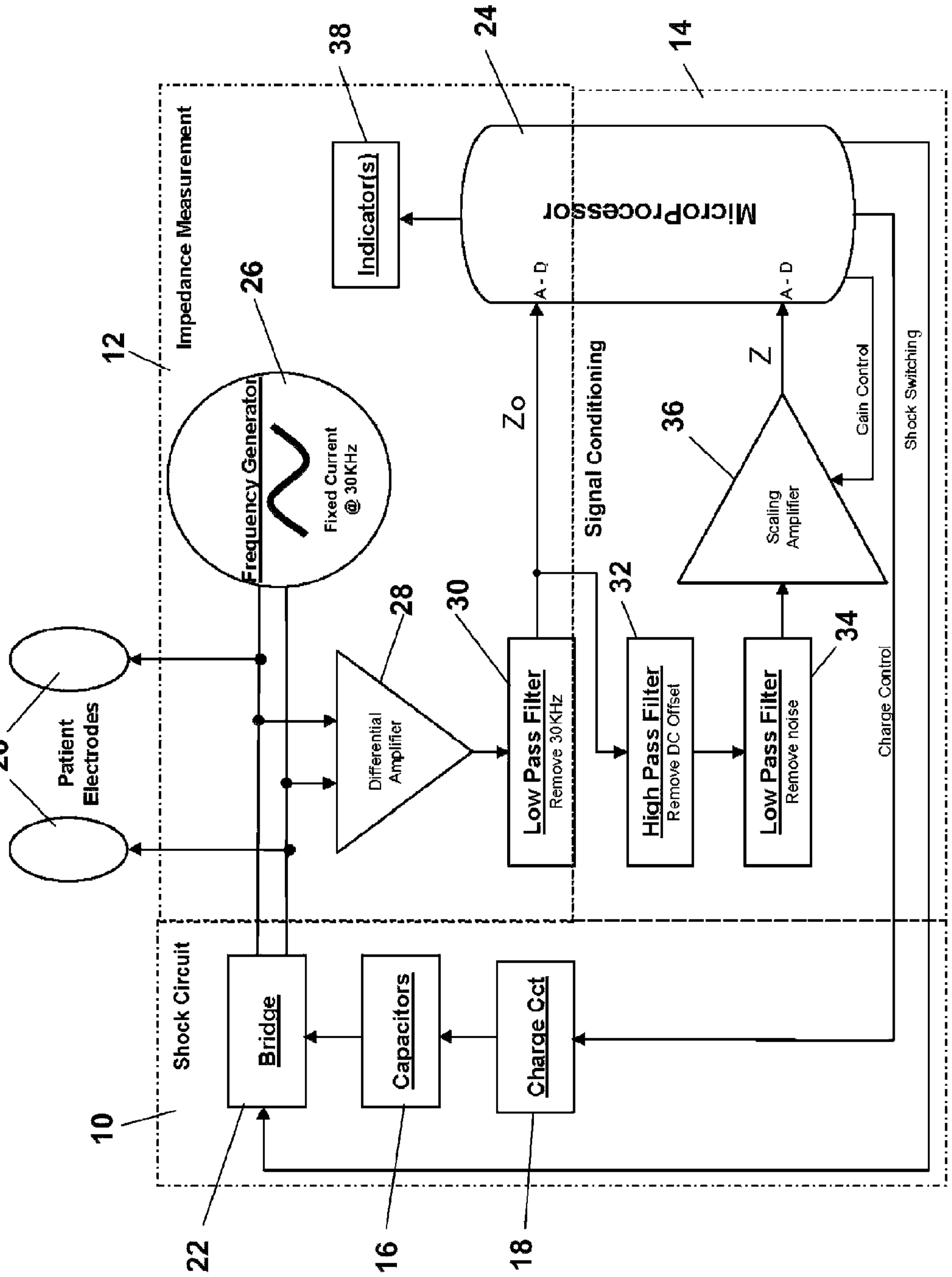
Shock Circuit
Bridge
Capacitors
Charge Cct
Impedance Measurement
Frequency Generator
Fixed Current @ 30KHz
Patient Electrodes
Differential Amplifier
Low Pass Filter
Remove 30KHz
Zo
Signal Conditioning
High Pass Filter
Remove DC Offset
Low Pass Filter
Remove noise
Scaling Amplifier
Z
Gain Control
Shock 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

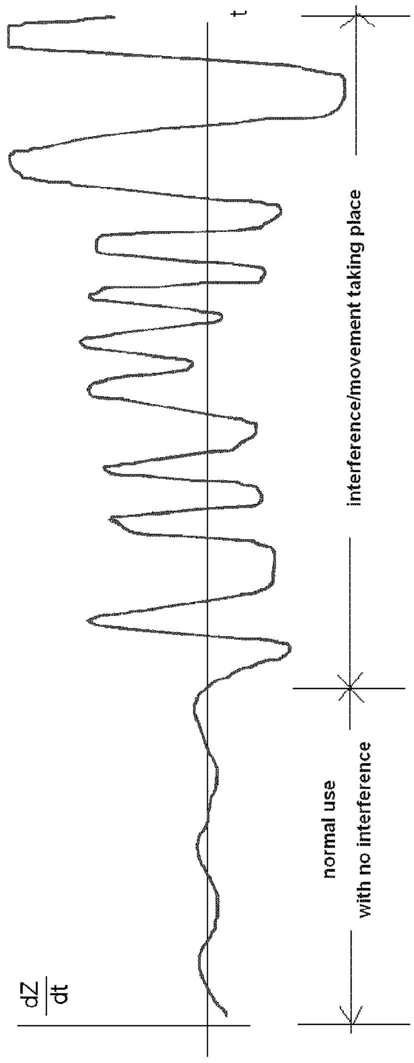
dZ/dt
t
normal use
with no interference
interference/movement taking place

Figure 2

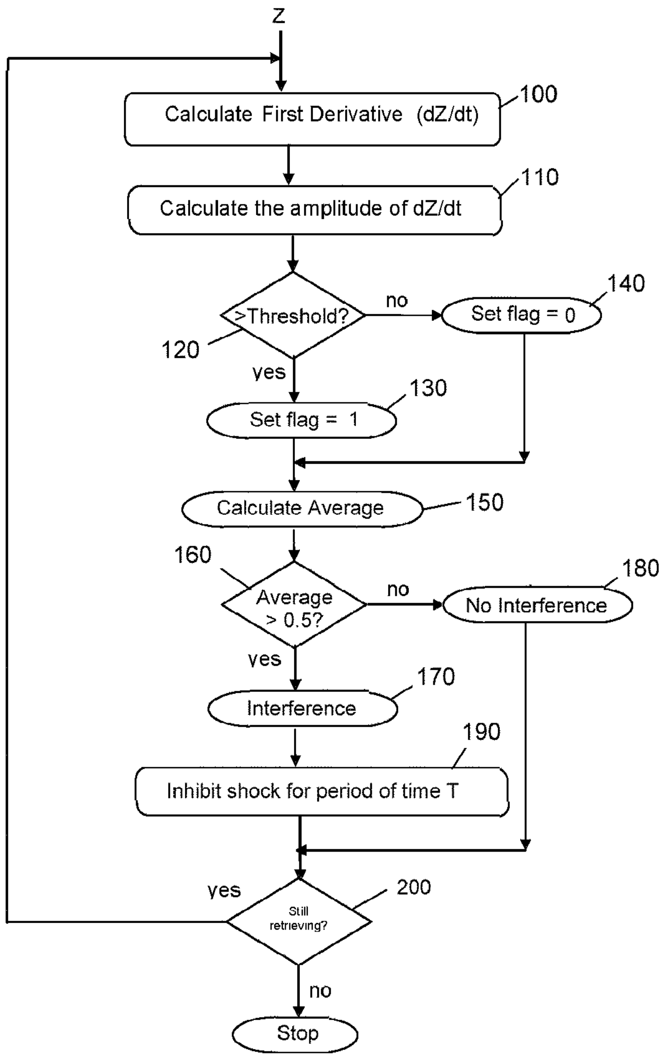
Z
Calculate First Derivative (dZ/dt)
100
Calculate the amplitude of dZ/dt
110
>Threshold?
no
Set flag = 0
140
120
yes
Set flag = 1
130
Calculate Average
150
160
Average > 0.5?
no
No Interference
180
yes
Interference
170
190
Inhibit shock for period of time T
yes
Still retrieving?
200
no
Stop

Figure 3

EXTERNAL DEFIBRILLATOR

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. application Ser. No. 13/990,059, filed May 29, 2013, now patented as U.S. Pat. No. 8,909,336, which is a national stage application under 35 U.S.C. §371 of International Application No. PCT/EP2011/071069, filed Nov. 25, 2011, and claims the benefit of European Application No. S2010/0746, filed Nov. 29, 2010, the disclosures of all of which are incorporated herein by reference.

This invention relates to an external defibrillator.

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.

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.

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

According to an aspect of the present invention, there is provided an external defibrillator as specified in claim **1**.

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.

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.

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.

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

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

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

FIG. **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.

Referring to FIG. **1**, an automated external defibrillator comprises three main sections: **10**, **12** and **14**.

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).

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 30 kHz 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 30 kHz 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.

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.

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**.

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, FIG. **3**, to detect interference conditions likely to cause the diagnostic algorithm to cause it to generate a false detection of a shockable rhythm.

First, however, reference is made to FIG. **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 FIG. **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.

Referring now to FIG. **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 0.75 s, step **150**. This is done by feeding a binary array of 128 elements (equivalent to 0.75 s 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**).

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

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.

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 0.75 s 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.

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.

The invention is not limited to the embodiment described herein which may be modified or varied without departing from the scope of the invention.

The invention claimed is:

1. A defibrillator comprising:
electrodes;
a processor; and
a circuit connecting the processor and the electrodes, wherein, when the electrodes are in contact with a patient, the processor performs operations comprising:
receiving a signal from the patient;
determining, from the signal, a measure of transthoracic impedance of the patient;
identifying, based on the measure of transthoracic impedance, that an interference condition is present, wherein the interference condition causes a false detection of a shockable rhythm in the patient; and
performing, based on the interference condition, one of: inhibiting the circuit from delivering a shock to the patient and preventing a diagnostic algorithm from detecting a shockable rhythm.

2. The defibrillator of claim **1**, wherein the interference condition is one of a movement of the patient and a touching of the electrodes by an operator.

3. The defibrillator of claim **1**, wherein when the electrodes are in contact with a patient, the processor performs further operations comprising:
establishing an electrocardiogram of the patient.

4. The defibrillator of claim **3**, wherein inhibiting the circuit from delivering a shock to the patient is independent of the electrocardiogram.

5. The defibrillator of claim **1**, wherein inhibiting the circuit from delivering a shock to the patient is performed for a predefined period of time.

6. The defibrillator of claim **1**, wherein when the electrodes are in contact with a patient, the processor performs further operations comprising:
identifying that the interference condition is present by forming a first derivative of the measure of transthoracic impedance with respect to a period of time to yield a first derivative; and
deriving a quantity of interference related to the first derivative.

7. The defibrillator of claim **6**, wherein when the electrodes are in contact with a patient, the processor performs further operations comprising:
determining if the quantity of interference exceeds a threshold level.

8. The defibrillator of claim **7**, wherein the quantity of interference is a measure of the number of times the amplitude of the first derivative exceeds the threshold level.

9. The defibrillator of claim **1**, wherein when the electrodes are in contact with the patient, the processor performs additional operations comprising:
converting the measure of transthoracic impedance from analog to digital, to yield a digital signal; and
using the digital signal for the identifying that the interference condition is present.

10. A method comprising:
receiving a signal from a patient via electrodes;
determining, from the signal and via a processor, a measure of transthoracic impedance of the patient;

identifying, based on the measure of transthoracic impedance, that an interference condition is present, wherein the interference condition causes a false detection of a shockable rhythm in the patient; and

performing, based on the interference condition, one of: inhibiting the circuit from delivering a shock to the patient and preventing a diagnostic algorithm from detecting a shockable rhythm.

11. The method of claim **10**, wherein the interference condition is one of a movement of the patient and a touching of the electrodes by an operator.

12. The method of claim **11**, further comprising:

establishing an electrocardiogram of the patient.

13. The method of claim **12**, wherein inhibiting the circuit from delivering a shock to the patient is independent of the electrocardiogram.

14. The method of claim **11**, wherein inhibiting the circuit from delivering a shock to the patient is performed for a predefined period of time.

15. The method of claim **11**, further comprising:

determining when the interference condition is present by forming a first derivative of the measure of transthoracic impedance with respect to a period of time to yield a first derivative; and

deriving a quantity of interference related to the first derivative.

16. The method of claim **15**, further comprising:

determining if the quantity of interference exceeds a threshold level.

17. The method of claim **16**, wherein the quantity of interference is a measure of the number of times the amplitude of the first derivative exceeds the threshold level.

18. The method of claim **11**, further comprising:

converting the measure of transthoracic impedance from analog to digital, to yield a digital signal; and

using the digital signal for the identifying that the interference condition is present.

* * * * *

专利名称(译)	外部除颤器		
公开(公告)号	[US9238146](US9238146)	公开(公告)日	2016-01-19
申请号	US14/561571	申请日	2014-12-05
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 ANDERSON JANICE		
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IPC分类号	A61N1/00 A61N1/39 A61B5/00 A61B5/0452 A61B5/053		
CPC分类号	A61N1/3918 A61B5/0452 A61B5/0535 A61B5/721 A61B5/7207 A61B5/7239 A61N1/3925 A61N1/3931 A61N1/3987		
优先权	S20100746 2010-11-29 IE 13/990059 2014-12-09 US PCT/EP2011/071069 2011-11-25 WO		
其他公开文献	US20150088215A1		
外部链接	Espacenet USPTO		

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ECU，以检测患者的心脏是否处于可电击的节律，并且当a时启用了电击输送电路（ 10 ）。诊断算法检测到可电击节律。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。