

A New Detection Algorithm for Implantable Cardioverter Defibrillator

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Summary

One of the most important sub-systems of implantable cardioverter defibrillator is the sensing stage, since it determines the sensitivity and specificity of the device to detect the rhythm condition of the patient. This paper aims to investigate a new detection algorithm for implantable cardioverter defibrillator, which operates fully automatically. The algorithm was implemented as a computer model and tested with intracardiac electrograms recorded (band-pass: 0.05 to 500 Hz; sampling rate: 1 – 4 kHz) under different rhythm conditions like sinus rhythm ($n = 18$), atrial tachycardia ($n = 16$), and ventricular tachycardia as well as fibrillation ($n = 139$) during electrophysiological tests or implantable cardioverter defibrillator implantation. The results of the tests were visually inspected on a beat-to-beat basis. In total 31934 events were classified by the algorithm (18758 as long intervals with cycle length > 300 ms; 13176 as short intervals). 195 out of the 13176 short intervals and 572 out of 18758 long intervals were incorrectly classified (short intervals: 1.48 %; long intervals: 3.05 %). In conclusion the new algorithm yield high sensitivity and specificity as known from conventional implantable cardioverter defibrillator algorithms but need no manual adjustments.

Key Words

Implantable cardioverter-defibrillator (ICD), ventricular sensing, detection of ventricular fibrillation

Introduction

Implantable cardioverter defibrillator (ICD) is an established therapy tool for treating ventricular tachycardias and preventing sudden cardiac death [1,2]. One of the most important subsystems in a single- as well as multichamber ICD is the sensing stage [3-5]. The proper function especially of the ventricular sensing stage is a prerequisite for high sensitivity and specificity of the device in detecting all kinds of arrhythmias. Reliable sensing of the ICD requires R-wave sensing without T-wave oversensing to avoid triggering of therapies due to doubled sensed QRS-T complexes especially in patients with large T-waves or patients with long QT syndrome [6,7]. In addition, the sensing circuitry has to reliably detect VF waves even if their amplitudes are small and unstable [3]. In the present ICD the required high sensitivity and

avoidance of T-wave oversensing is provided using algorithms, which change the detection level within a heart cycle (automatic gain control). After an event detection the maximal amplitude of this event is measured within a 50 ms time interval. Afterwards the sensitivity is lowered to 50 % of the event amplitude for 200 ms ("T-wave blanking"), avoiding T-wave oversensing. The disadvantages of the present design might be, that patients with large T-waves or long QT syndrome need fine tuning of the gain control algorithm by extending the T-wave blanking interval [6,7]. Since the sensing threshold is determined from the amplitude of the last event, consecutive events with large decline in amplitude are not detected.

This paper describes a new algorithm (ARGUS; Biotronik, Germany) to overcome the described draw-

backs of the present ventricular fibrillation (VF) detection algorithms. The new algorithm does not change the sensing threshold keeping it always at the most sensitive level and use the filter bank approach in combination with expert-based rules to identify not valid sense events, i.e., T-waves. After a detailed description, the testing of the algorithm using numerical methods is presented.

Materials and Methods

ARGUS Algorithm

The ARGUS algorithm consists of two major parts, the filter bank and the rule system to classify valid (i.e., R-waves and VF-waves) and invalid (i.e., T-wave) sensed events. Afterwards an x out of y criterion is used to determine whether or not a therapy should be delivered. In contrast to the conventional ICD algorithms the ARGUS needs no manual adjustments.

The filter bank consists of two band-pass filters taking the different spectral contents of R-, T-, and VF-waves into account. For illustration, Figure 1 shows an intracardiac signal filtered with two different band-pass filters. The wide band-pass filter (10 – 150 Hz) allows detecting R- and T-waves and provides high amplitudes. In contrast, the narrow band-pass filter with 20 Hz lower cut-off frequencies reliably rejects every T-wave.

In addition, the narrower band-pass reduces the signal amplitude of the R-waves from 10 to less than 5 mV, and it is expected that VF-waves with a spectral density similar to the T-waves may also be attenuated.

The filter bank approach uses the advantage of both band-pass filters: reliable rejection of the T-waves and undistorted signal amplitudes using the broad band-pass filter. The narrow band-pass filter ranges from 20 to 80 Hz and is called pacemaker-channel ("PMC") while the wider band-pass filter ("VF-channel, VFC") ranges from 10 to 150 Hz. In addition, the VFC sensing threshold is lower than that of the PMC channel to minimize the probability of VF-waveform undersensing. The sensing threshold is set above the noise level to 0.3 mV in VFC. The PMC sensitivity is set automatically in respect to the R-wave amplitude. The sensitivity will be increased, if the PMC detects no signal.

In each channel the event detection runs simultaneously. Afterwards the output of VFC and PMC are used to calculate valid and invalid events based on a set of 3 rules:

- Simultaneous detection (coincidence) in PMC and VFC is classified as a valid sensed event. The event

is classified as a "VF-wave", if the interval to the preceding event is shorter than the programmed VF limit, otherwise as an "R-wave" (Figure 1).

- A sensed event in VFC within the refractory period following a coincidence event (e.g., 300 ms for a VF detection rate of 200 bpm) is classified as an invalid sensed event (i.e., T-wave), and ignored (Figure 1).
- No sensed events in PMC but sensed events in VFC with an interval shorter than the detection rate (e.g., 200 bpm) are classified as VF-wave. Note: This rule guarantees that during undersensing in PMC (e.g., due to fine VF waves) the detection relies on the VF-channel with higher sensitivity and broader bandwidth (Figure 2).

Figures 1 and 2 illustrate the rules. The described algorithm was then realized in a computer model to test the performance with the help of recorded intracardiac electrocardiograms.

Testing of the Algorithm Using Computer Simulation and Recorded Intracardiac Signals

Intracardiac electrograms (IEGM) were recorded during electrophysiological investigations and during ICD implantation with a band-pass filter between 0.05 and 500 Hz at 1 up to 4 kHz sampling rate from 120 patients. The recordings include episodes of sinus rhythm, atrial flutter and fibrillation, ventricular tachycardias and ventricular fibrillation. The duration of the episodes ranges from 19.5 to 840 s. Figure 3 shows an example of intracardiac electrograms recorded during an ICD implantation with episodes of sinus rhythm, stimulation, and ventricular fibrillation.

In addition to the recorded IEGM, computer-generated waveforms were used to test the algorithm under specific and critical conditions (e.g., large T-waves with supraventricular tachycardia just below intervention rate). Table 1 summarizes the kinds of rhythms for in-vitro testing of the algorithm.

The influence of signal amplitude was simulated in 20 files representing different rhythm classes by artificially modulating the signal amplitude in 32 steps from 0.5 to 30 mV peak-to-peak. Furthermore adding 32 levels of noise simulated the impact of noise on the detection at 50 and 60 Hz (AC line frequencies in Europe and USA) to the 20 files at 32 levels of amplitude. Therefore, the ARGUS algorithm was tested at 20480 different amplitude and noise conditions.

The computer simulation of the algorithm automatically evaluates all the files and classifies all events as

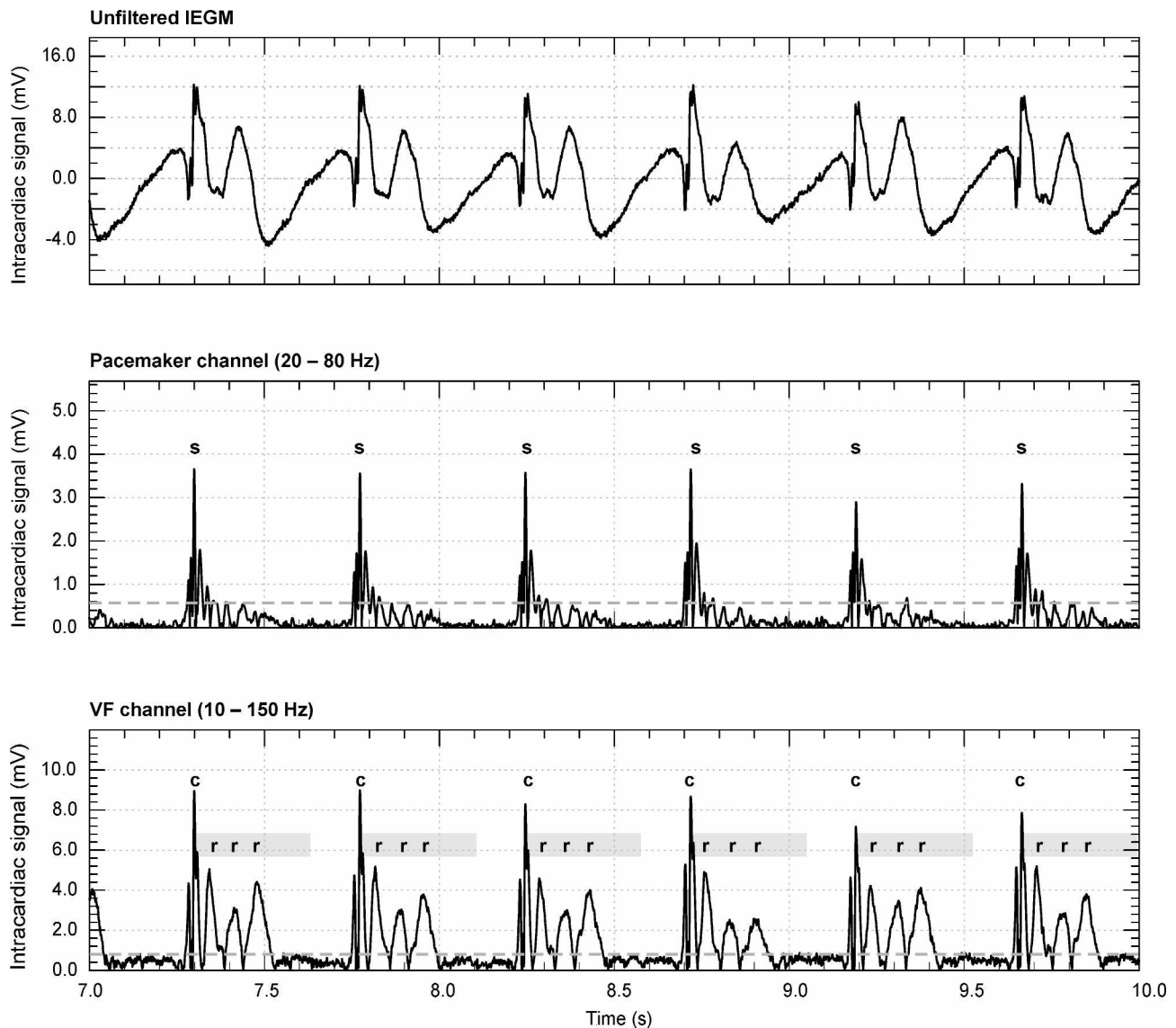


Figure 1. Intracardiac signal (upper trace: 0-250 Hz) filtered with two different band-pass filters (middle: 20 – 80 Hz, lower: 10 – 150 Hz) during sinus rhythm showing large T-waves. The band-pass filter with 20 Hz corner frequencies (pacemaker channel, PMC) rejects T-waves reliably, whereas the broadband filter (VF channel, VFC) gives higher signal amplitude. The dashed lines illustrate the sensing threshold in each channel. In PMC only the depolarization waves are detected (s). In VFC de- and repolarization waves are detected (c = coincidence detection, r = refractory sense). Since the R-waves are detected simultaneously in both chambers (rule 1) a 300 ms large T-wave suppression window is initiated, classifying the events of the VFC inside this window as invalid events (rule 2).

short (i.e., cycle length < 300 ms) or long intervals without any manual adjustment of the algorithm. Afterwards the classification of every event was checked visually on a beat-to-beat basis. The total number of correctly classified short and long intervals was counted. Especially the total of T-wave oversens-

ing in PMC and VF waves undersensing in VFC was especially investigated. Furthermore the expert rules of the algorithm were tested. Short intervals, which were sensed in VFC but rejected by the algorithm as invalid sensed events, were classified as overlooked short intervals.

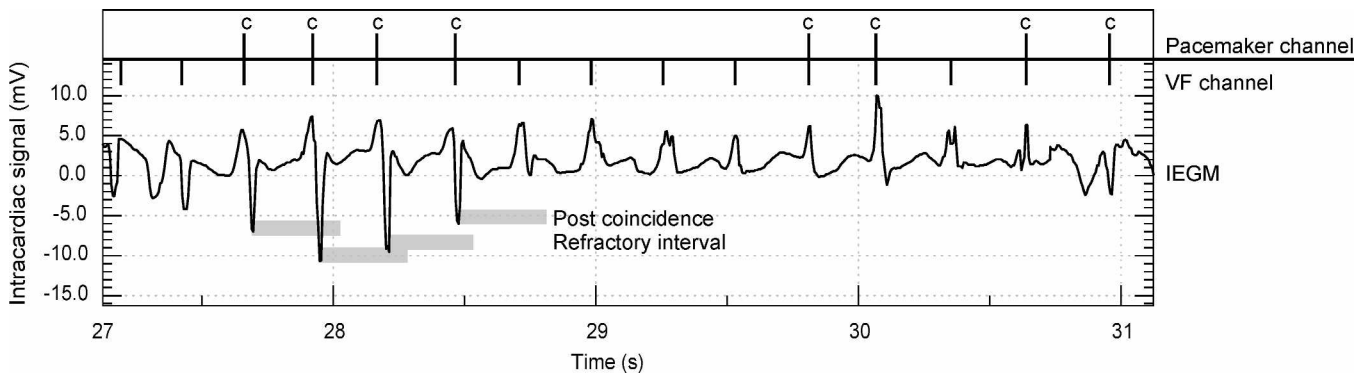


Figure 2. Intracardiac signals during ventricular fibrillation (VF). The detection in PMC and VFC (from Figure 1) are illustrated as sense markers in the upper trace. Simultaneously detected event in both channels ($c =$ coincidence) are valid sensed events triggering a refractory period of 300 ms (gray rectangles). The coincidence events in both channels within this refractory window are classified as short events (rule 1). During this VF episode undersensing occurs in PMC intermittently, but the VFC channel detects all events reliably. The VFC events without simultaneously detected events in the PMC and shorter than 300 ms as programmed intervention interval are classified as short intervals (rule 3).

Results

Testing of the Algorithm Using Computer Simulation and Real IEGM

Figure 3 shows a sequence of a shock-on-T induction of VF, VF, successful shock, and following sinus rhythm. The small circles at each event show that the ARGUS algorithm detects the event. The event markers are elevated, if the interval is classified as a short

interval. This example shows that the algorithm detected every event.

The results of the automatic calculation were then visually inspected on a beat-to-beat basis. In total 31934 events were classified by the algorithm. 18758 were classified as long intervals, 13176 as short intervals (< 300 ms). In none of these events a T-wave oversensing was observed in the PMC channel. Only 195 out of the 13176 short intervals were incorrectly

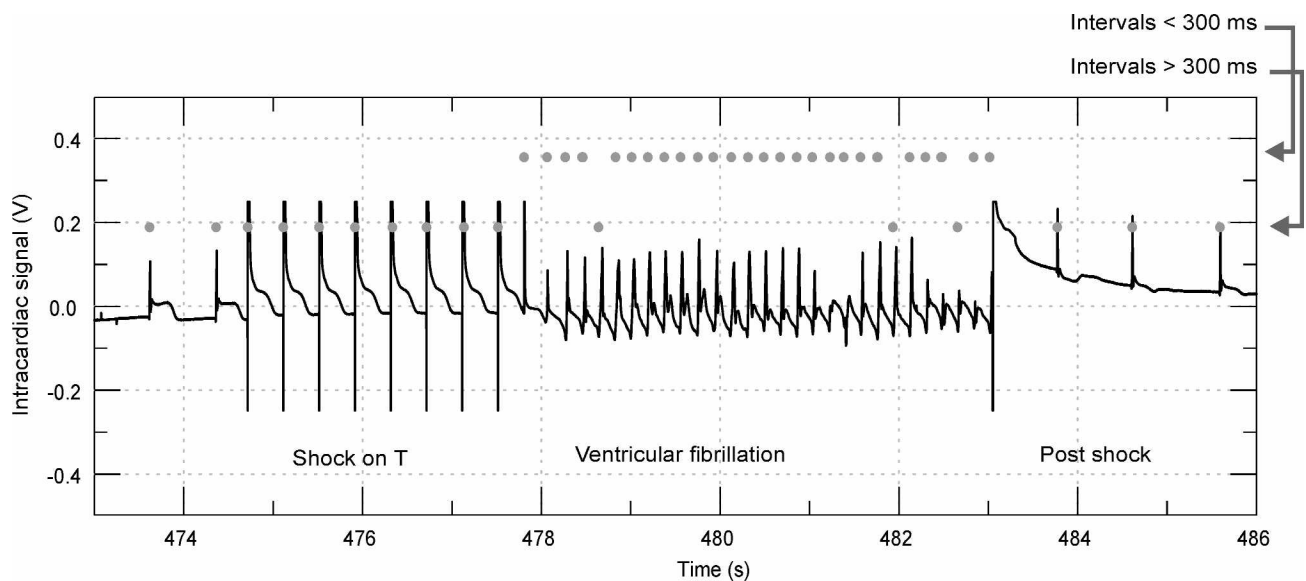


Figure 3. Classification of IEGM during induction of ventricular fibrillation (VF) using shock-on-T, VF, and sinus rhythm. Each circle represents a sensed event by the ARGUS algorithm. The circles are elevated, if the underlying cycle length of the event is classified as short (< 300 ms) and used for the VF counter. Three short cycles at 478.5, 482, and 482.7 s are detected but wrongly classified as long events. This is related due to intermittent PMC detection during VF.

Type of rhythm	Number of computer simulation files
Sinus rhythm	18 (3 with high T-waves)
Atrial tachycardia	16
Ventricular tachycardia (VT) below detection rate (200 beats/min)	9 (5 with AF/AT)
VT or ventricular fibrillation above the detection rate (> 200 beats/min)	130
Total	173

Table 1. Overview of the rhythm cases for the computer test of the ARGUS algorithm. A total number of 173 rhythm cases from 120 different patients were investigated. 14 of these cases were computer generated. The duration of the files ranges from 19.5 to 840 s. AF = atrial fibrillation; AT = atrial tachycardia.

classified, leading to a specificity of the algorithm for short intervals of 98.52 %. A total of 572 long events were incorrectly classified (96.95 %). The reason for that is intermittent sensing in the PMC channel during ventricular fibrillation; this lead to false classification of a VF wave as a T-wave (Figure 3).

The events classified as short intervals less than 300 ms increment the x counter of the x out of y criterion. In no case the misclassified T-waves or misclassified short intervals lead neither to a withheld nor to a wrongly delivered therapy if the x value was set to 75 % of the y value. Therefore the sensitivity and specificity of detecting the arrhythmia based on this in-vitro test is 100 %.

In the 20480 test files with several levels of noise at 50 and 60 Hz (AC line frequencies in Europe and USA) the ARGUS algorithm shows only one inappropriate withheld therapy under heavy noise conditions.

Discussion

The concept of two simultaneously sensing filters for the ventricular channel with different band-pass filter characteristic combines the benefit of both filters: The narrow band-pass filter PMC reliably detects the R-wave and, even more important, reliable rejects T-waves. In contrast, the broader band-pass filter VFC detects the R- as well as the T-wave. The filter characteristic of the VFC does not impair the signal amplitudes and in combination with the fixed high sensitivity even small VF waves are reliably detected. During sinus rhythm no T-wave oversensing was observed in

a total of 31934 events. During ventricular fibrillation a small number of VF waves (4.34 %) were classified as long intervals due to intermittent detection in the PMC channel.

The in-vitro results of the new detection algorithm show that the concept of two independent sensing channels leads to reliable detection of VF as well as rejection of T-waves. The algorithm classifying the detected events is highly specific for VF waves, but overlooks a small number of VF waves. Presently the small number of observed misclassification never led to a wrong therapy decision.

In conclusion, the new algorithm yields the same high sensitivity and specificity as conventional ICD algorithms but need no manual fine adjustments.

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