A New Approach for an Automated ECG-Morphology Based Dual Chamber Capture Detector

C. DE VOIR, R.A. SCHOMBURG
Micro Systems Engineering Inc., Lake Oswego, OR, USA

C. RAMACHANDRAN, C.S. LESSARD
Department of Biomedical Engineering, Texas A&M University, College Station, TX, USA

Summary

The increased functionality of implantable devices, including pacemakers and defibrillators, makes it necessary to automate tasks such as capture threshold search and signal amplitude measurements in order to relieve the physician of those duties. The article presents a new approach for the capture threshold detection for atrial as well as ventricular pacing. The algorithm analyzes the change of the signal morphology of the surface ECG to discriminate between captured and non-captured events. Six atrial and 13 ventricular recordings out of 17 patients of the capture test procedure have been analyzed event-by-event under offline conditions. In total, 615 events were classified in 538 captured and 77 non-captured events with neither false negtive nor false positive results. Nevertheless, further clinical examinations are necessary to confirm the early results and to test the algorithm under online conditions.

Key Words

Pacing threshold, electrocardiogram, automated follow-up, signal analysis

Introduction

In recent years, the capability and complexity of implanted medical products have grown with the inclusion of advanced functions and treatment modes. Although this is a broadly beneficial trend, it presents a challenge in terms of the increased clinical expertise and effort required for effective product support and utilization over a diverse patient population. Where feasible, we wish to free the physician for higher-level activities and decisions. It is therefore reasonable to examine ways in which we can automate certain common clinical tasks, which arise at device implantation or follow-up, such as capture threshold test or measurement of the intrinsic signal amplitude. In doing this, it is desirable to use measurement and computational resources, which can be provided external to the implanted device. One of these essential tasks, in the case of pacing functions, is the accurate determination of patient threshold levels. Once known, they guide the selection of stimulus amplitudes to provide reliable capture, while avoiding unnecessary energy consumption within the device. A critical element, in the development of any automated method for pacing threshold measurement, is the unequivocal determination of capture. An algorithm performing this function must contend with numerous interfering factors, and perform as accurately as an experienced human observer. Practical application requires that the algorithm has minimal effect on current consumption of the implant device, and be compatible with (and simplify the procedure for) many device types. In addition, it should be usable with atrial and ventricular signals, be independent of specific event morphologies, and be unaffected by the pacing artifact or after-potential characteristic of any particular lead.

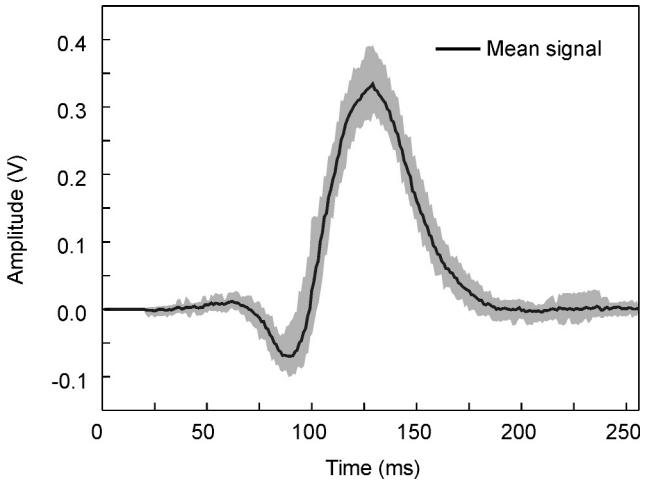

Figure 1. Composite reference event bounded by extrema of raw reference event values.

Our investigations have shown that these requirements are effectively satisfied using morphology-based event discrimination methods. The resulting algorithm, and related verification process, are described below, and have been developed for incorporation within the next generation of device programmers.

Materials and Methods

Capture Detection Algorithm

The capture detection algorithm (CDA) is written in an object-oriented language [1] using a integrated development environment (IDE) [2]. Simulations were performed on a standard desktop computer. The input data are pacemaker threshold tests formated as four channels (one marker, three surface ECG) from the ECG output of a pacemaker programmer (TMS1000, Biotronik) sampled at 1024 Hz and 12 bits per channel (DAQCard700, National Instruments, USA). These recordings were also used to verify the accuracy of the CDA.

Pacemaker implant follow-up is the setting intended for the use of CDA. Thus, the CDA will be integrated into the programmer software. The requirements for the operation of the CDA are as follows. The CDA requires a start signal from the user, and outputs termination, and error signals that communicate completion of classification or the need for operator intervention. The CDA must have access to the programmed values for pacing rate and AV-delay to set the appropriate measurement window (MW) length. The CDA must also receive pace, sense markers, and a time-sampled ECG data stream of at least one channel. Additional simultaneous ECG channels can also be used.

The CDA provides two outputs. The principal output of the CDA is an event-by-event classification of capture/non-capture. This datum is used for adjusting subsequent pacing output voltage in the search for a threshold. Second, error conditions are returned by the CDA to inform the operator of the need for adjustment of the pacemaker to control the rhythm, or that signal input is compromised.

The CDA operates in two main phases, a reference definition phase, and an event classification phase. The reference definition phase collects two sets of reference events, spontaneous rhythm events, and unequivocal pacer-controlled rhythm events. Obtaining the latter may require adjustment of the basic pacing rate and the AV-delay to ensure pacer control. An example of a reference pacing event (composed from the individual events in a paced rhythm) is shown in Figure 1. In addition, the reference definition phase starts a continual noise threshold calculation from sample-by-sample data.

From the two sets of reference events, parameters and limits are generated for the second main phase of the CDA, the classification phase. In this second phase, every marked event is evaluated against the two sets of references, paced and spontaneous. Event by event, the classification of capture/non-capture is returned as a datum to continue a threshold search. In some conditions, such as, excessively high dynamic noise threshold, the CDA returns error signals. Therefore, some outputs result in a modification of the threshold search while other errors inform the operator the need for mitigation. A flow diagram of the CDA is displayed in Figure 2.

ECG Records

We analyzed six atrial and 13 ventricular threshold tests of 17 patients (58% male, 42% female, mean age 75.3 years, range 61 – 85 years). The indications for implantation were SSS bradycardia, atrial fibrillation, atrial flutter, and ventricular tachyarrhythmia. Implanted devices (all from Biotronik) were Actros SR (2), Actros DR (2), Dromos DR (3), Philos DR (6), Tachos DR (1), Gemnos IV (1), MycroPhylax (1), and Phylax XM (1). All devices were equipped with a bipolar lead. The time from implantation to data collection ranged from 5 to 1961 days with a median of 495 days.

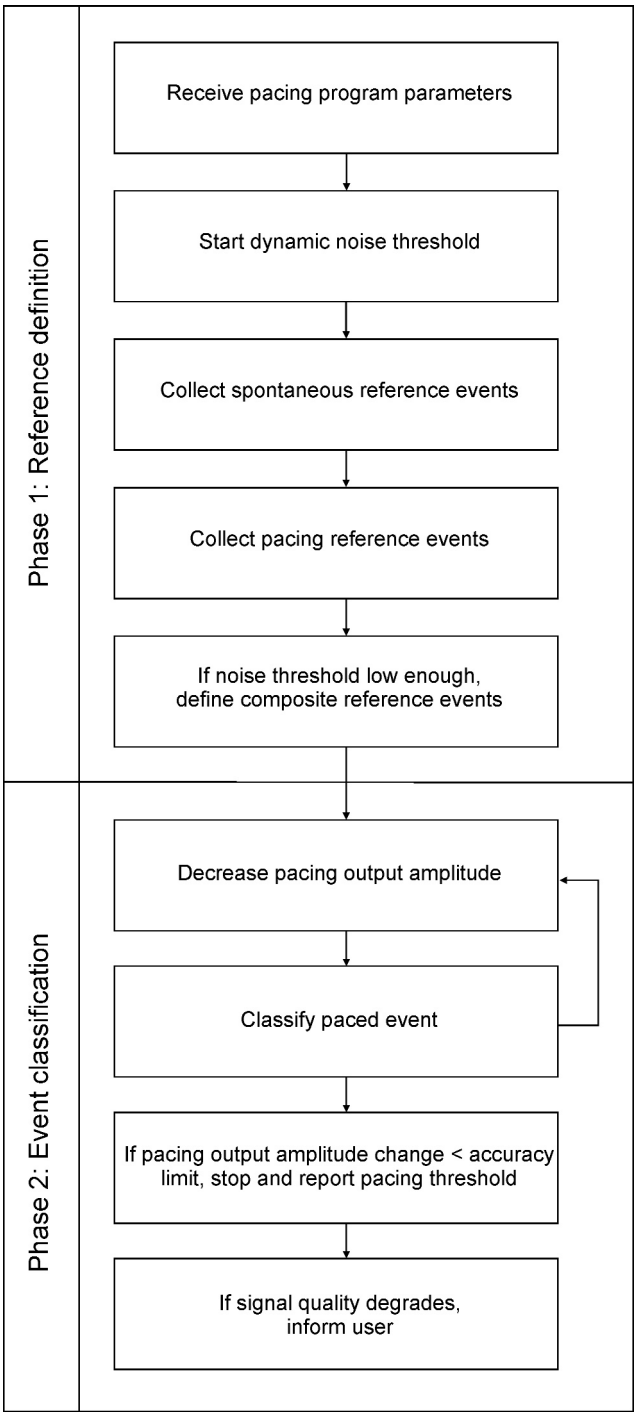

Figure 2. Flow diagram of the capture detection algorithm.

Study Design

The accuracy of the CDA was verified by a comparison of algorithm results with an event-by-event human review of the above pacing threshold test clinical data using the following methods. The defining criteria for each event occurs in an MW, which is the time window comprising 512 ms for atrial pacing and 256 ms for ventricular pacing. The MW commences with the pacing marker and terminates after the defined number of samples in the ECG channel under consideration. Within the MW, the three main criteria that define an event are

- peak delay (PD),
- signal amplitude (SA), and
- shape.

The PD is defined as time from the pacing marker to the most prominent peak found within the MW. A paced event earlier than the PD range is premature; if later than the PD range or entirely absent from the MW it is considered late. The SA is the voltage potential from the isoelectric line to the most prominent peak in the MW. An event in the classification phase must exceed the noise threshold (NT) and approximate the mean amplitude of the reference events. Signal shape is the similarity of the morphology of the event to that of the reference events formed during the definition phase. Therefore, the reference definition phase (the initial ten pacing events) is inspected to familiarize the human reviewer with the fundamental timing relationships and morphologies used to analyze subsequent events in the event classification phase. The classification phase follows, and the human reviewer observes pacing and sensing markers while comparing each marked event with the criteria determined in the definition phase. The reviewer understands that the pacing output voltage is being systematically reduced, thus, the ECG record evolves to non-captured events.

Results

An example of a ventricular paced reference event is shown in Figure 3. Figure 4 shows some outcomes of event classification, the results of which are tabulated in Table 1. The first marker identifies the ECG event as paced. For the human reviewer it is 'on-time', of typical amplitude, and shape. The second, third, and fifth markers identify paces that yield no events above the NT. The fourth marker is correctly identified as a sense. The sixth marker identifies a pace that does not capture but yields a spontaneous event that differs visually in morphology. By following this methodology, the human reviewer established the "golden" reference classification of captured and non-captured events. In

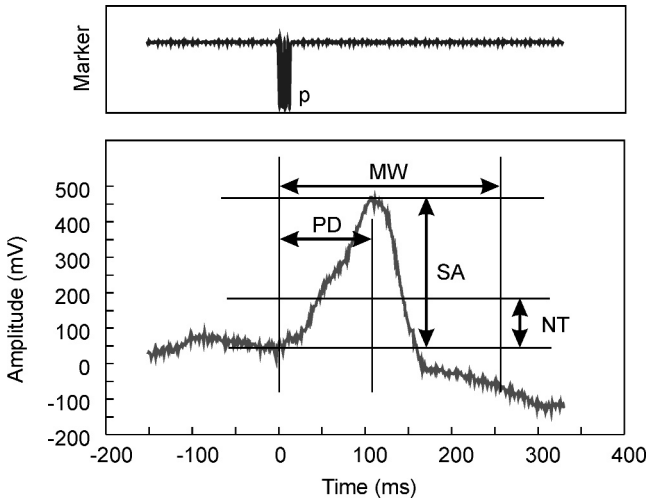

Figure 3. Classification criteria within the measurement window (MW). The MW for the ventricular paced event here is 256 ms. The peak delay (PD) for this event is 105 ms, and the signal amplitude (SA) is 420 mV (rescaled due to ECG output amplification). The dynamic noise threshold (NT) is continually adjusted sample-by-sample. The NT is about 30% of the SA here and represents a minimum threshold that the amplitude of an event must exceed in order to be discriminated from collinear noise.

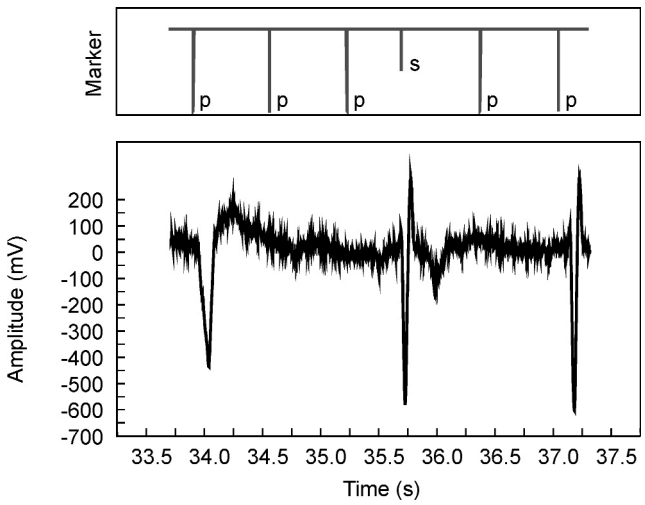

Figure 4. Event classification outcomes.

total, 615 events were classified and successfully discriminated into 538 captured and 77 non-captured events. The comparison of the classification output of the CDA to the evaluation of the human resulted in a count of true positive, false positive, false negative, and true negative events (A, B, C, and D, respectively in Table 2). The sensitivity and specificity were 100%.

Discussion

In an off-line test of clinical recordings of pacing threshold tests, the CDA correctly discriminated effective from ineffective pacing stimuli, fulfilling one of the essential requirements of a pacing capture algorithm [6]. Unlike full-time implanted capture algorithms, the CDA only operates on the programmer during the implant or follow-up pacing threshold test. Within this scope, the CDA can free the physician/operator to focus on higher-level tasks. Additionally, the CDA will improve the repeatability and reliability of pacing threshold tests by executing an optimized search algorithm. The CDA performs this at no additional current-cost to the implanted device.

Algorithmically, the CDA includes certain improvements with respect to other algorithms in the literature [3]. An adaptive noise threshold, generated in the definition phase, rejects line-frequency, quantization, and smaller artifacts [4]. Event pre-processing also compensates for baseline drift. The algorithm indicates to the user if the signal morphology is inconsistent or the lead system is compromised. Unlike other algorithms,

Event number	Marker	Peak delay	Amplitude	Morphology	Classification
1	Pace	On-time	Adequate	Matches	Capture
2	Pace	Late	Below noise	No match	Non-capture
3	Pace	Late	Below noise	No match	Non-capture
4	Sense	Ignored	Ignored	Ignored	Ignored
5	Pace	Late	Below noise	No match	Non-capture
6	Pace	Late	Adequate	No match	Non-capture

Table 1. Capture classification outcomes of Figure 4.

		Human reviewer	
		Captured events	Non-captured events
CDA	Captured events	A = 538	B = 0
	Non-captured events	C = 0	D = 77

Table 2. Event classification accuracy of capture detection algorithm. A = true positive, B = false positive, C = false negative, and D = true negative events.

CDA has no requirement for specific event morphology, amplitude of after-potential, or special parameters entered by the user other than initial programming to control the intrinsic rhythm [5]. CDA needs only consistent reference events from which it defines exemplars for sense and pace [6]. The algorithm is intended for use with surface ECG conveniently available from the output of a programmer. In fact, we were pleased to find that the algorithm was also robust to nonstandard lead placement of the three surface leads, such as, all leads placed within the outline of a handprint over the sternum. We have tested an earlier version of the algorithm on wideband IEGM and anticipate that the algorithm would also be successful on IEGM signal input through a low artifact fractal lead. Since it resides on the programmer, CDA can be used with any implanted device that can be addressed through this interface.

Future improvements will integrate the CDA into a pacing threshold test on the next programmer platform. At that time, a larger, on-line clinical study will be performed allowing a more significant statement of accuracy of this algorithm.

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Contact
Chris de Voir
Micro Systems Engineering, Inc.
6024 S.W. Jean Road
Lake Oswego, OR 97035
USA
Fax: +1 503 635 9610
E-mail: de_voir@msn.com