Evaluation of an Event Classifier for
Pacemaker Ventricular Evoked Response Detection

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Abstract

In order to improve depolarization waveform classification, a new classifier for pacing evoked response vs. lead polarization was developed. The classifier was based on identification of polarization characteristics, considering deviations to be indicative of capture. Waveform classifier features were trained using saline tank and acute patient (pt) data. A total of 31 pts with 9 lead models were studied acutely prior to pacemaker implant. Following placement of lead(s), pts were paced at 1.0–4.8V (bipolar and unipolar), paced at specific AV delays to induce fusion, and paced to determine pacing threshold using an external pacemaker. The first 12 pts were part of the training set and the remaining 19 pts represented the test set. Over 24,000 ventricular pacing pulses were analyzed. Test set sensitivity was 99.5% and specificity was 97.2%. In conclusion, the capture event classifier showed improved fusion classification and a greater lead tolerance.

1. Introduction

Historically, clinicians measure the pacing threshold at pacemaker follow-up by visual electrocardiographic determination of pacing depolarization (capture) while varying the pulse amplitude. The pacing output amplitude is then typically set to approximately twice the pacing threshold measured in volts.

During the past several years, pacemakers have become available that automatically and continuously evaluate the success of the ventricular pacing pulse to depolarize myocardium [1,2]. This capability has permitted such pacemakers to automatically set the pulse output to meet the changing pacing threshold. Additionally, if non-capture is detected, the device quickly issues a back-up pace at higher pacing output.

This feature is designed to conserve battery charge so that pacemaker longevity is enhanced and increase the likelihood of ventricular capture in the event of increasing pacing threshold. The pacing threshold may change for a variety of reasons, including lead maturation, changes in medication, lead micro-dislodgment, pathologic changes or physiologic changes such as exercise [3,4].

Although pacemakers that provide automatic output are available, fusion of intrinsic and paced depolarizations has caused misclassification rates of up to 25% [1]. True capture waveforms that are misclassified as non-capture (e.g., as a result of fusion) cause unnecessary back-up pacing pulses and unnecessary threshold searches that waste the battery charge that the feature is designed to preserve.

Additionally, the pacing lead selection of previous devices has been limited to leads specifically treated to attain low polarization artefact and to unipolar pacing [5]. The event classifier described here was designed to reduce the incidence of false non-capture detection due to fusion, permit the use of leads with greater polarization artefact, and permit the use of all pacing/sensing polarity combinations.

2. Methods

2.1. Event classifier

An event classifier was developed to separate ventricular evoked response and lead polarization artifact. In order to maximize the detection of fusion depolarizations as capture, polarization artifact was characterized through the use of 6 waveform features. The observation that polarization artifact waveform morphology is relatively constant (if visible) between leads and pulse amplitudes was exploited by classifying waveforms that were not similar to polarization artifact as capture. For lower polarization leads and lower pacing amplitudes, the polarization artifact is typically non-existent at normal pacemaker amplification and therefore poses no difficulty for the simplest of waveform classifiers. However, using higher polarization leads and/or higher pacing amplitudes, a more sophisticated event classifier is required. An exemplary polarization waveform for these conditions is shown in Figure 1. Figure 2 shows a typical evoked response waveform.

The morphology of evoked response depolarization waveforms may vary significantly due to fusion with intrinsic depolarizations, variations in pulse amplitude (a result of additive polarization effects), and patient-to-patient variability. The waveform features are indicted in Figures 1 and 2 (upper case) and are defined as follows:

INGR1: Sum of the positive differences* until the first negative difference.

INGR2: Sum of the absolute value of all differences starting with the first negative difference.

CNT1: Number of samples in INGR1.

CROSS: Flag = 1 if at least one sample following CNT1 samples is a positive difference.

MAX_POS: Maximum positive difference for all samples following the first x samples.

NEG_AMP: Maximum negative difference.

*Amplitude difference = sample amplitude – blanking period amplitude.

Seven parameters are defined to classify waveforms given the measured features above. These parameters (lower case italics shown in Figures 1 and 2) are:

w: Width of analysis window.

x: Number of samples to exclude before measuring MAX_POS.

$w1$: Limit on CNT1.

zn: Absolute limit on NEG_AMP.

zp: Limit on MAX_POS.

$a1$: Lower limit on AREA* (below which is non-capture).

$a2$: Higher limit on AREA (above which is capture).

*AREA may equal INGR1 + INGR2 or INGR2 depending upon the value of CNT1 (see Figure 3).

Once the waveform features are calculated, the algorithm of Figure 3 classifies events as capture/non-capture. A sufficiently negative amplitude immediately classifies a waveform as capture. Otherwise, a low area classifies a waveform as non-capture. If the positive portion of the waveform is wide and high, or the area is large, capture is classified. In the case of medium area, a cross from negative to positive values indicates capture. In other cases, non-capture is classified.

2.2. Procedure

Patients of at least 18 years of age and undergoing initial pacemaker implant or replacement were included in the study. An external pacemaker was connected to atrial (if present) and ventricular intracardiac leads. The hardware was controlled using software residing on a PC which simulated the pacemaker microprocessor. The PC allowed real-time display of intracardiac electrograms and markers, plus stored data for offline analysis.

A pacing/sensing analyzer was used to measure pacing thresholds. Once adequate lead placement was determined, the external pacemaker was connected to the implanted lead(s) and indifferent electrode temporarily placed in the pulse generator pocket.

Three procedures were attempted on each patient:

1. Fixed rate overdrive A/V or ventricular pacing. Unipolar and bipolar pacing/sensing at 1.0, 2.0, 3.6, and 4.8V.
2. A/V pacing at 5 different AV delays designed to invoke fusion. (In patients with atrial and ventricular leads and AV conduction.)
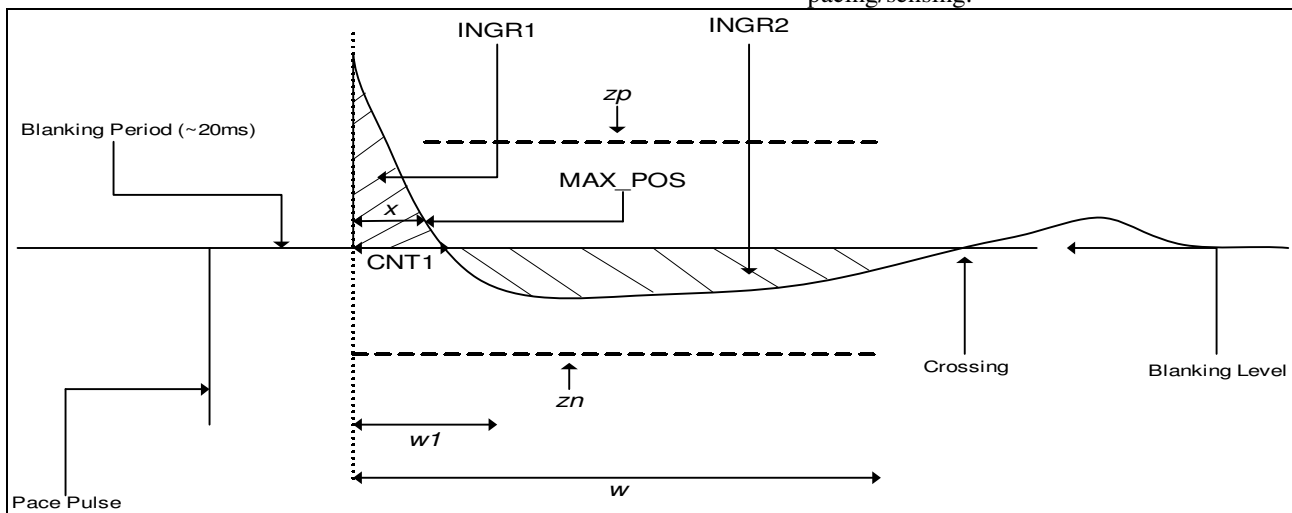3. Automated threshold search decrementing from 3.6 and 4.8V with unipolar and bipolar pacing/sensing.

Figure 1. Schematic polarization waveform with measured waveform features in upper case and waveform discrimination parameters in lower case italics. Informational messages are indicated by mixed upper and lower case.
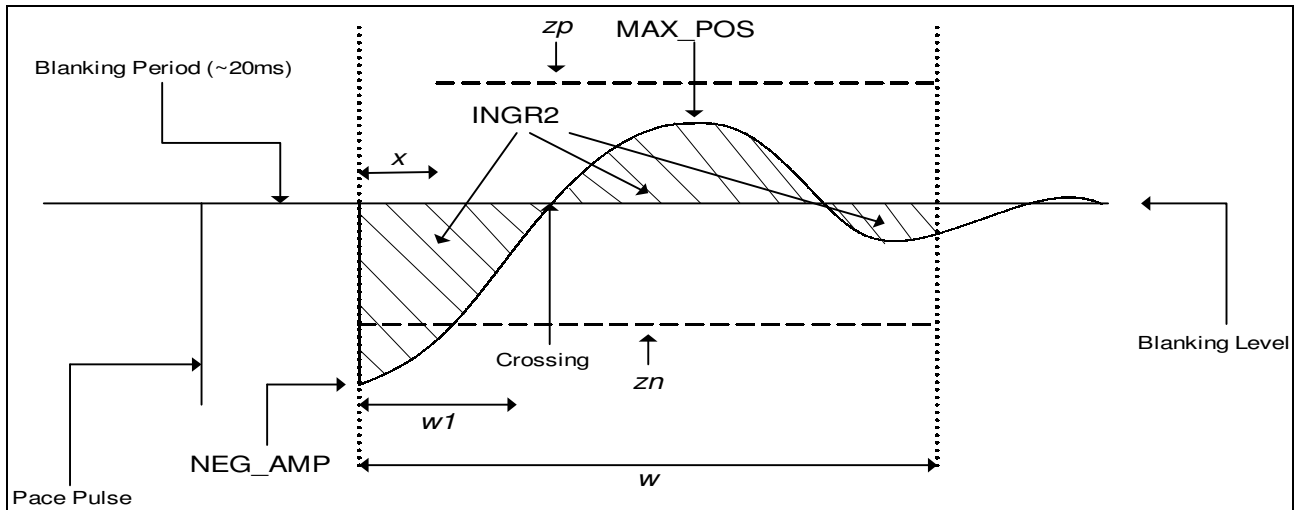
Figure 2. Schematic evoked response waveform with measured waveform features in upper case and waveform discrimination parameters in lower case italics. Informational messages are indicated by mixed upper and lower case.
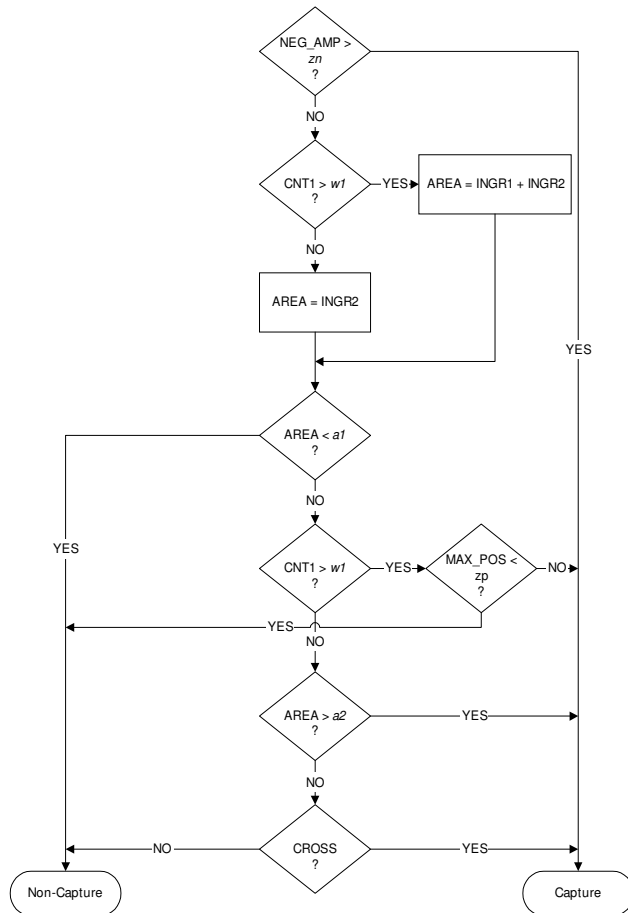

Figure 3. Flow chart of event classifier algorithm.

2.3. Data analysis

Electrogram data recorded were replayed offline to generate the set of waveform features. The features were imported to an Excel spreadsheet that determined capture/non-capture classification. The electrogram data were visually inspected to determine the true classification and false positives/false negatives were identified.

3. Results

3.1. Clinical data

There were 21 male and 10 female patients studied that ranged in age from $45 - 90$ years (76 ± 9 years). Twelve patients were tested in DDD mode and 19 in VVI mode. A total of 33 leads were tested as follows: Biotronik PX BP (19), Biotronik SX BP (3), Medtronic 4092 (3), St. Jude 1472T (2), Medtronic 5028 (2), Intermedics (1), Biotronik RX BP (1), Medtronic 4058M (1), and CPI 4261 (1). A total of 3 chronic leads were studied with 2 patients having chronic leads explanted and replaced with acute leads.

3.2. Detection accuracy

Adjustments were made to the event classifier algorithm during data collection of the first 12 patients which comprised the training set. The algorithm was frozen and the 19 additional patients were designated the test set. There were a total of 24,246 ventricular depolarizations analyzed for correct determination of capture.

The training set results are shown in Table 1. The

sensitivity and specificity of detection were 98.8% and 100%, respectively. Sixty-eight of the false negatives occurred in Patient 4. They were a result of a recurrent, unusual evoked response waveform with low amplitude. The remaining 15 were a result of fusion. Of the patients in the training set, 1 patient had sensitivity less than 99% and 0 patients had specificity less than 99%.

Table 1. Training Set Detection Accuracy

	Detected as Non-Capture	Detected as Capture
True Non-Capture	113	0
True Capture	83	6588

The test set detection accuracy is given in Table 2. The sensitivity and specificity of detection were 99.5% and 97.2%, respectively. All 88 false negatives were a result of fusion. Of the patients in the test set, 1 patient had sensitivity less than 99% and 2 patients had specificity less than 99%.

Table 2. Test Set Detection Accuracy

	Detected as Non-Capture	Detected as Capture
True Non-Capture	173	5
True Capture	80	17293

4. Discussion

An event classifier algorithm for the discrimination of capture and non-capture to permit an automatic capture control algorithm for implanted pacemakers has been described. The algorithm was shown in acute clinical studies to be sensitive to the detection of capture even in the presence of fusion, while being specific to the detection of non-capture in a variety of leads, polarities, and pacing amplitudes.

The only detection errors in the training set were a large number of false negatives in Patient 4. The algorithm parameters were not adjusted to accommodate these capture waveforms because it was thought that doing so would cause the detection of true non-capture to be compromised. Therefore, Patient 4 was considered an outlier for evoked response detection. It was not expected that the event classifier would be adequate for 100% of patients. A separate, signal quality check (SQC) algorithm (not described here) was designed to automatically select patients with adequate evoked response and lead polarization characteristics prior to activation of the automatic capture control algorithm. It is expected that the SQC algorithm would determine Patient 4 to be unacceptable for further event classifier analysis and therefore not permit automatic capture control in this patient.

Detection of true capture as non-capture leads to wasted battery charge through the issuance of unnecessary backup pulses and threshold searches. However, detection of true non-capture as capture causes the absence of a ventricular depolarization, and in the absence of an intrinsic rhythm potentially leads to ventricular asystole. The 5 false positives in the test set occurred in 2 patients with high polarization leads (Medtronic 4092 and CPI 4261). All had uncharacteristically large negative artifact at low pacing amplitudes with no accompanying positive-going artifact. The 4092 lead had all 4 false positives in bipolar pacing/sensing configurations only. No errors occurred during unipolar pacing and/or sensing configurations. This appeared to be a result of a low microsurface area ring electrode. The 4261 lead had its single false positive in unipolar pacing/sensing. Again, the SQC algorithm is designed to reject patient/lead/polarity combinations that would cause the event classifier to incorrectly detect non-capture as capture resulting from high polarization artifact, as is the case with these two combinations.

A limitation of the study was its acute nature. The classifier is currently being evaluated in chronically implanted pacemakers as part of the PACC multicenter clinical study.

References

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