A New Dual Chamber Cardioverter-Defibrillator with Left Atrial Pacing Support

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Summary

The first DDÄ-DDDR (Ä = AE - Active discrimination & Electrogram) dual chamber implantable cardioverter-defibrillator with left atrial pacing support was implanted on January 24, 2000. This is a true dual chamber ICD with three atrial tachyarrhythmia detectors and tiered therapies in the atrium. It can also detect junctional tachycardia that is treated with atrial therapies. Reliable atrial detection is possible with an enhanced atrioventricular discrimination algorithm in the ventricle. The original SMART Detection™ algorithm, with 95.1 % specificity at essentially 100 % sensitivity, has been augmented with an active discrimination scheme, SMART Detection™ II, that provides improved discrimination in the case of 1:1 atrioventricular rhythm. The device also incorporates a full feature DDDR pacemaker with enhanced hysteresis, PMT termination, and mode switching. To prevent atrial fibrillation, the device also supports biatrial bipolar pacing.

Key Words

ICD, atrial fibrillation, active discrimination, supraventricular tachycardia, junctional tachycardia, coronary sinus, biatrial pacing

Introduction

Since the first dual chamber implantable cardioverter defibrillator (ICD) was implanted, a succession of dual chamber ICDs have appeared in the market [1,2-4]. At least in the U.S., the majority of ICD implants are now with dual chamber devices [5]. The primary indication for the dual chamber ICD has been the need or anticipated need for dual chamber pacing. However, with the addition of the atrial sensing lead, the dual chamber ICD makes possible enhanced AV discrimination that can reduce the incidence of inappropriate therapy due to supraventricular tachyarrhythmia (SVT). Inappropriate therapy due to SVT has been reported with an incidence rate as high as 41 % in single chamber ICDs [6-9]. One of the better atrioventricular (AV) discriminating dual chamber ICD [10] has been the Phylax AV (Biotronik, Germany). In U.S. clinicals during 1999, ventricular tachycardia specificity of 95.1 % with essentially 100 % sensitivity has been reported. This compares very favorably with other discrimination algorithms [11-18]. The discrimination capability of the Phylax AV was based on the SMART Detection™ AV discrimination algorithm which, through extensive interval testing, can determine whether a high ventricular rhythm is of ventricular or supraventricular origin. The weak point of all these AV discrimination algorithm has been 1:1 AV rhythms. While sudden onset has been able to differentiate, somewhat successfully, between sinus tachycardia and other tachycardia, the further differentiation between ventricular tachycardia (VT) with retrograde conduction into the atrium and SVT conducting down to the ventricle is not possible if the SVT is paroxysmal.

The majority of the dual chamber ICDs can be classified according to the NASPE/BPEG defibrillator code, the NBD code, as VVE-DDD(R) [19]. They do not provide therapies for atrial tachyarrhythmia.

True dual chamber ICDs, with the NBD code of DDE-DDD, have been introduced recently [14,20,21]. These

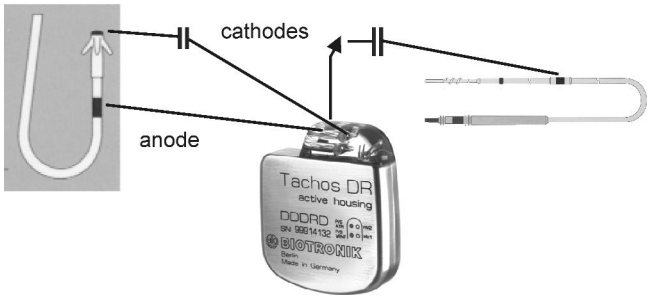

Figure 1. Biatrial bipolar pacing supports a regular right atrial lead (left) and a coronary sinus lead (right).

true dual chamber ICDs use the same AV discrimination algorithm of their VVE-DDD cousins. Since these devices are implanted in patients with frequent episodes of atrial tachyarrhythmia, even with the relatively small percentage of inappropriate ventricular therapies, we expect the actual number of inappropriate ventricular therapies to become large. A significant improvement in AV discrimination is needed for an effective true dual chamber ICD.

Another concern that has been expressed with regard to atrial tachyarrhythmia therapy has been the release of thrombus into the circulatory system. The standard procedure is not to attempt automatic atrial fibrillation (AF) therapy, and maybe even atrial flutter (Afl) therapy, 72 hours after the onset of the tachyarrhythmia. Since it is desirable to wait up to one day, in the hope that the AF episode terminates spontaneously [21], a concurrent episode of ventricular tachyarrhythmia, e.g., VT, may develop during this wait. After successful termination of the ventricular arrhythmia, it is necessary to redetect the AF. It would be desirable that the delay for the AF therapy is not restarted to avoid running into the 72-hour limit due to repeated episodes of VT during the wait.

Material and Methods

The first implant of the Tachos DR™-M (Biotronik) took place at the Bakoulev Institute for Cardiovascular Surgery, Moscow, Russia, on January 24, 2000. The patient, a 62-year old male, with chronic heart ischemia and coronary artery disease, was suffering from paroxysmal VT, resistant to antiarrhythmic drugs. The patient has a history of multiple coronary bypasses dating back to 1991. Sinus bradycardia and intraatrial conduction disturbance with 132 ms P-wave duration were aggravated by paroxysms of atrial fibrillation. The Tachos DR™-M was implanted into the patient to enable both synchronous dual chamber and biatrial pacing along with standard ICD therapy.

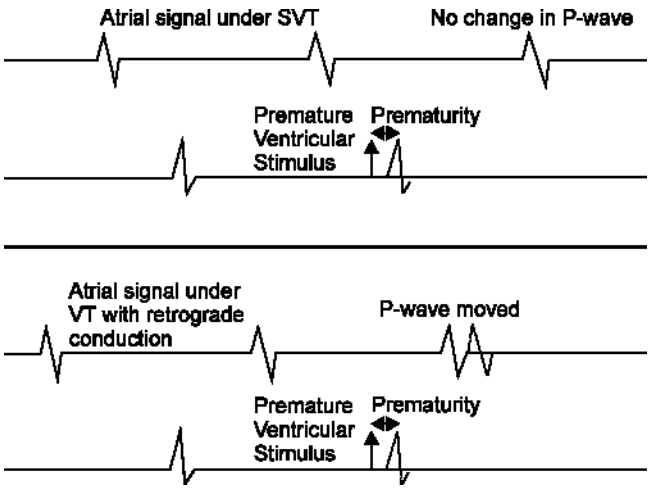

Figure 2. Active 1:1 rhythm discrimination.

The Tachos DR™ has a volume of 48 cc and weighs 88 grams. The Tachos DR™-M is the biatrial version of the device. The M version has a five port header (the standard Tachos DR™ has a four port header) that provides built-in support for a coronary sinus lead for pacing the left atrium. The particular left atrial pacing configuration supported is tripolar with the right atrial tip and the coronary sinus ring being the cathodes and the right atrial ring the anode [22]. This is the biatrial (BiA) bipolar pacing scheme. It is depicted in Figure 1. The coronary sinus electrode, when activated, is coupled through a DC-current blocking capacitor to the rest of the circuit. This is a safety feature that is not available when using an external adapter [23].

The coronary sinus electrode can be programmed to be switched in, biatrial mode, or out, right atrial mode. The programming is "permanent" (until a new program is sent down). The biatrial bipolar scheme was chosen because it is relatively cost effective from an energy point of view.

The Tachos DR™ supports an enhanced SMART Detection™ AV discrimination algorithm. In the case of a 1:1 rhythm, active discrimination is undertaken using isolated ventricular paces in the ventricle and analyzing its effect on the detected atrial P-waves [24]. This is illustrated in Figure 2. The hypothesis under test in the active discrimination SMART Detection™ II is that the 1:1 rhythm is caused by:

- H0: VT with retrograde conduction
- H1: SVT

With an SVT, hypothesis H1, the ventricular pulse being only about 80 ms premature cannot penetrate the AV node to conduct retrograde to the atrial electrode in the RAA. Under hypothesis H0, the retrograde conduction disturbs the atrial rhythm. In our tests we found that, in the latter case, the disturbance can either increase or decrease the detected P-P interval. The tests are repeated a number of times with different amount of prematurity. We only need about 2 instances of P-P changes to confirm the H0 hypothesis. To avoid being pro-arrhythmic, the ventricular pacing pulses are delivered 8 QRS complexes apart.

The complete SMART Detection™ algorithm is depicted in Figures 3 and 4.

In the enhanced 1:1 rhythm detection, junctional tachycardia (JT) is also detected by checking that either the P-R interval or R-P interval is within the programmed limit, typically 40 ms. Except for JT, the SMART Detection™ does not influence the atrial detection process. The detection zones are illustrated in Figure 5.

In the ventricle, even though there are three therapy zones, only two detectors are used, namely the VT and VF detectors. With a single detector, episodes of VT can be detected and therapy, based on the last average rate, delivered promptly. In the atrium, since atrial tachycardias (AT) are not life threatening, we want to increase our specificity by using two detectors, AT-1 and AT-2, in the AT zone. The VT, AT-1 and AT-2 detectors use up-down counters. The VF and AF detectors use X out of Y criteria. When a junctional rhythm is detected, the AT-1 counter is incremented.

The VT detector uses the result of the SMART Detection™ algorithm to increment its count. The AT-1 and AT-2 detectors just use atrial rate as the primary criterion.

SMART Detection™, which uses both atrial and ventricular information, is the default VT detector. However, it is also possible to use a ventricular only detector, which is ventricular rate, stability and sudden onset based. The physician has the choices shown in Table 1.

In the AT-1 zone, sudden onset is used as detection inhibitor (the AT-1 counter is not incremented if there is no sudden onset) to avoid detecting sinus tachycardia and ectopic atrial tachycardia. In the AT-2 zone, stability is a therapy discriminator. If the rhythm is unstable (slow AF), atrial anti-tachycardia pacing

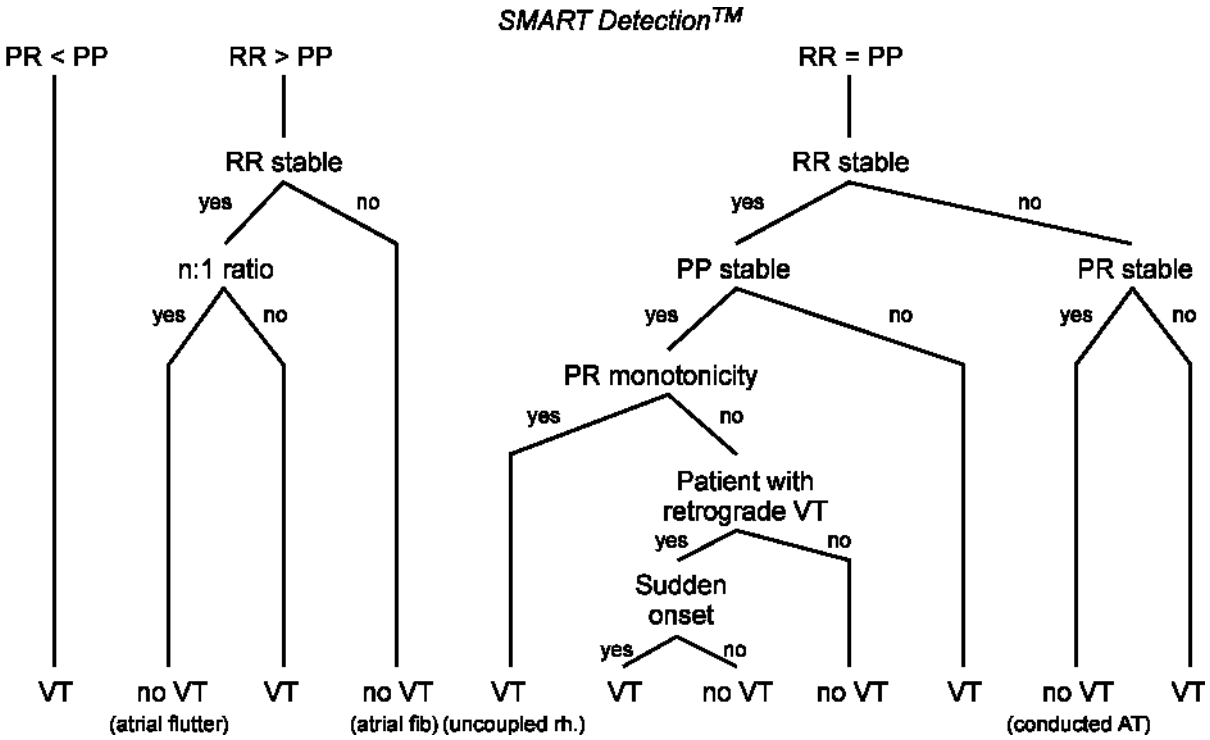

Figure 3. Enhanced SMART Detection™.

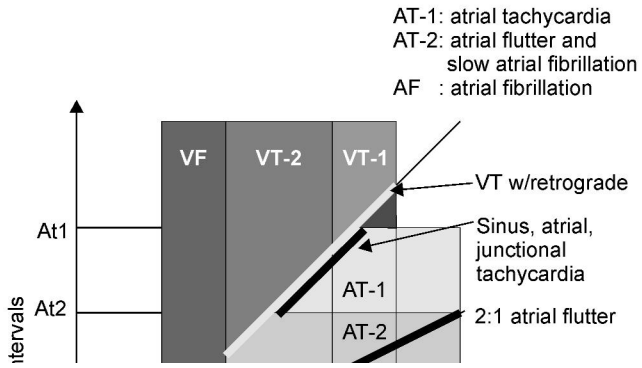

Figure 4. Enhanced 1:1 detection.

(ATP) is skipped and the first therapy is an atrial high frequency (HF) burst.

A useful diagnostic feature of the Tachos DR™ is its ability to create and save an IEGM record when no therapy is delivered in the course of an episode of high ventricular rate due to inhibition by the AV discrimination algorithm, be it the SMART Detection™ algorithm or the simpler ventricular-only criteria.

In addition to tachyarrhythmia detection and therapy features, the Tachos DR™ also offers a full feature DDDR pacemaker, which is PVARP based for improved PMT avoidance.

Some of the advanced bradycardia features offered are:

- Separate normal and post-shock bradycardia parameter sets.
- Mode switching with programmable rates. A programmable up-down counter is used. Switch can occur with just 4 fast atrial events.
- PMT termination. After 16 paced events, if the R-P interval is longer than the programmed (bradycardia) PVARP and the PVARP extension (used when a PVC is detected), then the next ventricular pace is skipped.
- Enhanced hysteresis: night rate, scan hysteresis and repetitive hysteresis [25].

Options	VT-1	VT-2
Standard	SMART Detection	
Polymorphic VT in VT-2	SMART Detection	Ventricular Only (rate only)
Not recommended	Ventricular Only (rate + sudden onset + stability)	

Table 1. VT detection criteria.

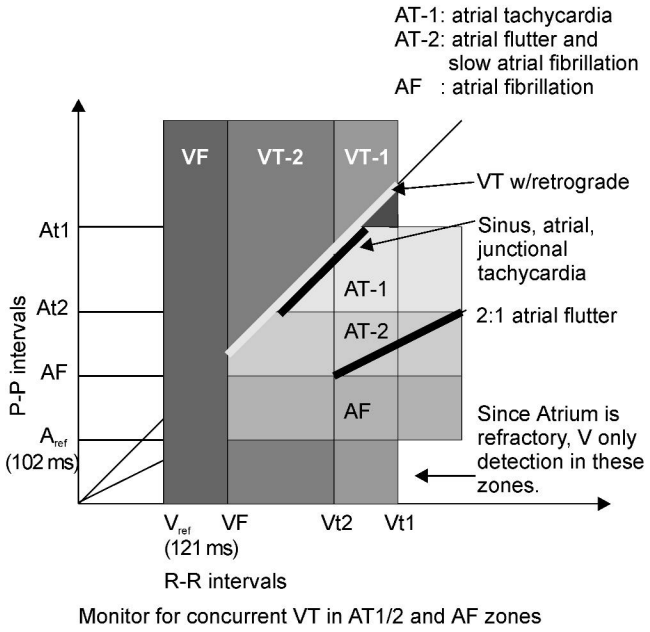

Figure 5. Tachos DR™ detection zones.

Improved diagnostic features are:

- Up to 34 minutes of stored dual channel IEGM. The memory can be divided into 7-127 records (one for each detection/redetection) with programmable post detection duration.
- Up to 13.6 hours of PP, PR and RR interval storage.

Intraoperative Measurements and Tests

Standard intraoperative measurements were performed on the 3 electrodes implanted into the patient along with the Tachos DR™-M ICD.

The Synox SX 53-JBP electrode positioned into the right atrium (RA) for sensing and pacing demonstrated the P-wave amplitude of 6.5 mV (slew rate of 1V/s) and the stimulation threshold of 0.3 V (at impedance of 700 Ω). The V278 lead with 2 ring electrodes for BiA pacing and a shock coil for defibrillation was implanted into the coronary sinus (CS). The threshold of 2.3 V

VT-1	VT-2	VF	AT-1	AT-2	AF
ATP1	ATP3		ATP5	ATP7	
ATP2	ATP4		ATP6	HF1	HF2
CV1	CV2	DF	CV3	CV4	CV5

Table 2. Therapy modules available.

Episode Summary

S : SMART algorithm used for detection
V : Ventricle-only algorithm used
* : Detection resulted from a timeout

> : Permanent Program was changed

				EGM
9	Date 24.01.2000 16:50:27		S	
	Episode duration: 35 sec			
	1	RAMP VT2	S	YES
	2	RAMP VT2	S	YES
	3	SHOCK VT2 2 J 1s 57 Ω	S	YES
		TERMINATION		YES
> 8	Date 24.01.2000 16:43:16		S	
	Episode duration: 2 min 4 sec			
	1	RAMP VT2	S	YES
	2	RAMP VT2	S	YES
	3	SHOCK VT2 2 J 1s 62 Ω	S	YES
		TERMINATION		YES
> 7	Date 24.01.2000 16:35:34		S	
	Episode duration: 33 sec			
	1	RAMP VT2	S	YES
	2	SHOCK VT2 2 J 1s 61 Ω	S	YES
		TERMINATION		YES
> 6	Date 24.01.2000 16:21:59		S	
	Episode duration: 12 sec			
	1	BURST VT1	S	YES
		TERMINATION		YES
> 5	Date 24.01.2000 16:18:21		S	
	Episode duration: 13 sec			
	1	BURST VT1	S	YES
		TERMINATION		YES
> 4	Date 24.01.2000 16:09:01		S	
	Episode duration: 33 sec			
	1	BURST VT1	S	YES
	2	BURST VT2	V	YES
	3	SHOCK VT2 1 J 1s 62 Ω	V	YES
		TERMINATION		YES
> 3	Date 24.01.2000 15:48:43			
	Episode duration: 46 sec			
	1	BURST AT1		YES
	2	HF BURST AT2		YES
		TERMINATION		YES
> 2	Date 24.01.2000 15:44:57			
	Episode duration: 1 min 57 sec			
	1	BURST AT1		YES
		TERMINATION		YES
> 1	Date 24.01.2000 15:43:58			
	Episode duration:			
		TERMINATION		YES

Figure 6. Print-out of the interrogation protocol with 9 arrhythmia episodes in which both the SMART II and ventricular-only algorithms have been tested.

at 250 Ω impedance was measured in the BiA pacing mode with the cathode at the distal pole of the RA lead and the anode at both proximal pole of the RA electrode and the ring pole of the CS lead. The right ventricle (RV) Kainox SL 75/16 lead with 2 shock coils implanted into the apex showed the pacing threshold of 0.5 V (with the slew rate of 3.2 V/s) and the R-wave amplitude of 25.2 mV.

During the implantation procedure several safety therapeutic and diagnostic options have been tested that are printed out in the interrogation protocol (Figure 6). Total 9 tachyarrhythmia episodes have been tested in which the following therapies have been applied:

- 9 ventricular ATP (2 successful),
- 3 atrial ATP (2 successful),
- 2 ventricular shocks (2 successful).

A 1 J shock was delivered to induce ventricular fibrillation that resulted due to cordarone treatment either in VT with the cycle length (CL) of 270 ms or ventricular flutter with the CL of 240 - 250 ms. Figure 7 presents an episode of selective VT therapy in 2 zones (VT1 and VT2) and successful termination of ventricular arrhythmia by a 2 J cardioversion shock.

Diagnostic features of the device supported by PP, PR and RR intervals storage are demonstrated in Figure 8 depicting the RR interval trend of the episode with the shock delivery.

Also the BiA pacing option aimed to avoid AF paroxysms in the patient has been activated. Figure 9 shows the ECG with the P-wave duration of 100 ms at BiA-pacing that is profoundly shorter in comparison to the 132 ms long P wave characteristic for the patient without pacing. The patient feels well during the 2-month follow-up period with activated BiA pacing on the background of administered 80 mg sotalol per day. No AF and VT/VF episodes are registered in contrast to several short AF episodes per day observable prior to the device implantation.

Conclusions

The Tachos DR™ is a true dual chamber ICD. Its active discrimination feature makes it the first ICD with an active sensor. Thus, our claim that it is the first DDÄ-DDDR device. This is not the standard NBD code. The Ä, which can also be written as AE, is used to indicate that we have here an Active discrimination device based on Electrogram measurement.

To date, we have tested this active discrimination feature in human under sinus and atrial tachycardia conditions. Our first patient unfortunately did not exhibit VT with retrograde conduction. As we expand the

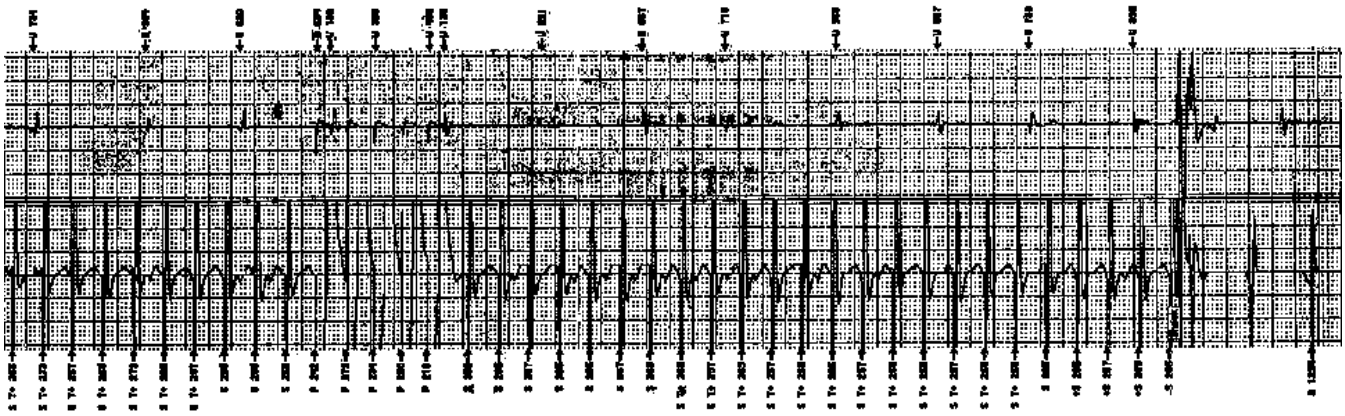

Figure 7. Episode of selective VT therapy in 2 zones (VT1 and VT2) and successful termination of ventricular arrhythmia in the patient SH by a 2 J cardioversion shock.

patient population, we expect to achieve confirmation under all 1:1 rhythm conditions. This has been verified already in animal studies.

In summary, the Tachos DR™ key features are:

- Dual chamber tachyarrhythmia detection and therapy.
- Active AV discrimination for improved performance with 1:1 rhythms, making it a DDÄ-DDDR device.
- Three atrial detection zones.
- Long HF burst with ventricular support for improved effectiveness.
- Forced ventricular termination.
- Detection of atrial therapy caused ventricular tachyarrhythmia, and mitigation.
- Atrial redetection ratchet with intervening ventricular tachyarrhythmia.
- Far field QRS oversensing mitigation and avoidance.
- Giant T wave avoidance.
- Up to 34 minutes of stored dual channel IEGM and up to 13.6 hours of PP, PR, RP interval storage.

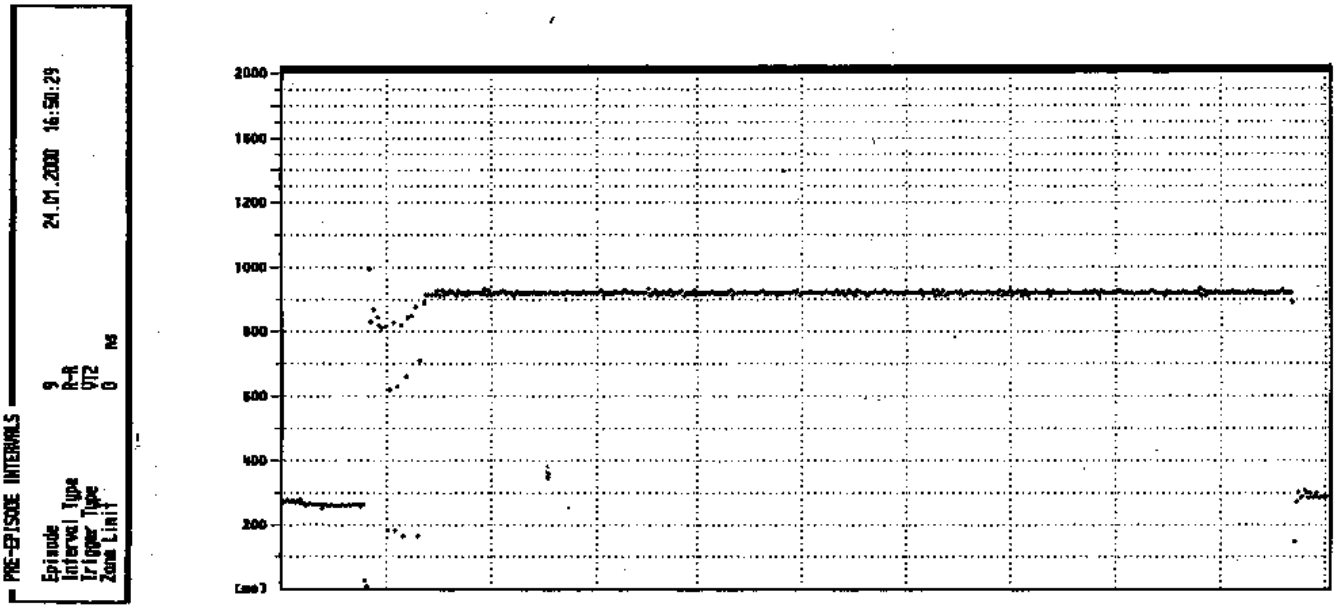

Figure 8. Print-out of the RR interval trend during the VT episode with the shock delivery.

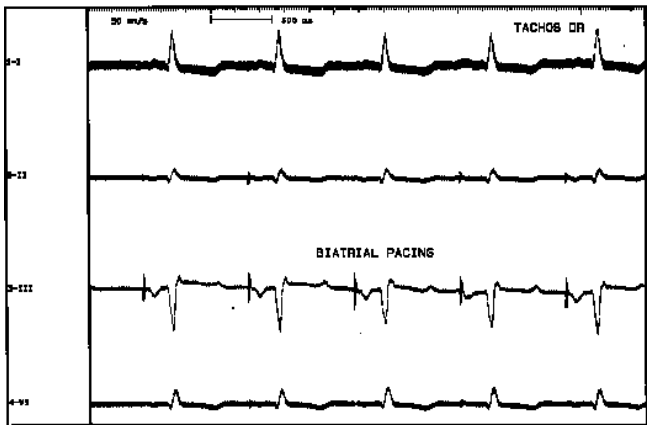

Figure 9. Surface ECG recorded during biatrial pacing with the ICD.

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