Introduction to a new "X out of Y" Mode-Switching Algorithm in Inos² CLS and Logos Dual-Chamber Pacemakers

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Summary

Paroxysmal atrial fibrillation (PAF) may complicate pacemaker therapy in up to 60% of the patients with dual-chamber systems. Rapid tracking of PAF may cause severe symptoms and hemodynamic deterioration. Thus, refined algorithms providing AV-synchronous pacing during sinus rhythm and preventing high ventricular rates during PAF are desirable. This comprehensive paper introduces a new mode-switching algorithm that uses a fixed (Inos) or programmable (Logos) number of short intervals out of 8 consecutive atrial intervals for the detection of PAF and subsequent switching to a non-tracking mode. This paper discusses the algorithm and the optimizing of the programming of parameters that may indirectly influence the mode-switching sensitivity and specificity. The introduced mode-switching concept is designed to maintain and improve the sensitivity and fast reaction achieved in devices with the "mode-conversion" feature. For the optimal mode-switching algorithm, adequate sensing, detection of low fibrillation potentials and insensitivity to far-field R-wave signals are mandatory. A programmable mode-switching algorithm may be advantageous in reacting to individual rates of arrhythmia and atrial sensing performance, but the use of very restrictive or very liberal criteria should be avoided. Both extremes may lead to mode oscillations. While short blanking periods allow the detection of all short P-P intervals, they should not result in inappropriate mode-switching due to atrial oversensing. However, the advanced diagnostic functions allow the physician to rectify any improper adjustments at follow-up.

Key Words

Paroxysmal atrial flutter/fibrillation, mode-switching, diagnostic functions, dual-chamber pacemakers, atrial blanking

Introduction

Different concepts have been developed to achieve, at least partial, AV-synchronous pacing in patients with dual-chamber pacemakers and paroxysmal atrial fibrillation (PAF) or flutter. Until recently, PAF has been regarded as a contraindication [1] for atrial-tracked dual-chamber pacing (DDD, DDDR, VDD), because the atrial arrhythmia could be tracked at the upper tracking limit (UTL). However, programming a low UTL (e.g., between 90 and 100 bpm) may be of limited use in patients with sinus tachycardia and 2:1 block and may still lead to symptoms during PAF that occurs at rest with tracking at the UTL. Pacing in the DDI or DDIR modes do not provide AV synchrony in patients with AV block and chronotropic competence.

Thus, algorithms have been introduced that are designed to enable the system to switch to a non-tracking pacing mode when PAF occurs. The ventricle is then paced at a rate independent of the atrial rate. The algorithm switches back to a tracking mode at the end of the atrial tachyarrhythmia. The importance of such automatic mode-switching algorithms may increase. First, new data on the occurrence of PAF in paced patients reveal a high prevalence of atrial arrhythmias in 30 to 60% of these patients [2]. Second, new pacing strategies are increasingly applied to suppress PAF with: biatrial or multisite pacing [3], continuous overdrive pacing algorithms, pacing in concert with high-dose drug treatment, and dual-chamber pacing in patients with PAF after AV node ablation. Thus, an increasing number of patients with known PAF are treated with dual-chamber pacemaker therapy. But even if these therapeutic interventions are able to suppress atrial fibrillation to a high extent, adequate pacing therapy during the remaining atrial fibrillation episodes must be provided for the large group of patients with dual-chamber pacemakers and recurrent PAF [4].

The requirements of automatic mode-switching are a specific reactivity to atrial tachyarrhythmia and avoidance of inappropriate mode-switching triggered by other factors, far-field R-wave oversensing, for example. High sensitivity to PAF and a quick reaction are, thus, major prerequisites for a reliable algorithm. The ventricular rate during the mode-switching episode should be adequate for hemodynamic needs, and a sudden rate drop should be prevented through a ventricular rate-smoothing algorithm. Finally, quick and reliable detection of the end of the atrial arrhythmia is necessary to regain beneficial AV-synchronous pacing.

This paper introduces a new concept for automatic mode-switching using a statistical "x out of y" criterion in Inos² CLS (DDD-CLS) and Logos (DDD) pacemaker systems by BIOTRONIK (Berlin, Germany). The paper presents the advantages and possible limitations together with clinical implications of this mode-switching concept, as well as hints on programming the parameters associated with mode-switching. The use of stored diagnostic data is explained with a clinical example. These statistical features may assist in identifying symptomatic or asymptomatic problems of the device that can be traced to sub-optimal programming or problems with special atrial arrhythmias, such as slow atrial flutter or very low atrial fibrillation potentials.

The Technical Concept

A new algorithm for detecting PAF has been integrated into "Closed Loop Stimulation" (CLS) pacemaker systems (Inos^2 CLS, Inos^{2+} CLS) [5,6] and the Logos DDD pacemakers. The algorithm is based on a statistical evaluation of the P-P intervals, using an "x out of y" criterion. This concept yields a higher specificity than mode-switching that reacts to only single premature events ("beat-to-beat" mode-switching) and a faster reaction than mode-switching using a mean atrial rate.

In Inos devices, mode-switching is performed when 5 out of 8 consecutive P-P intervals are shorter than the mode-switching interval (Figures 1 and 2). For the Logos devices, the "x" is programmable, between 2 and 7, and the "y" is 8 consecutive P-P intervals. The mode-switching detection rate is programmable between 100 and 180 bpm for the Inos devices,

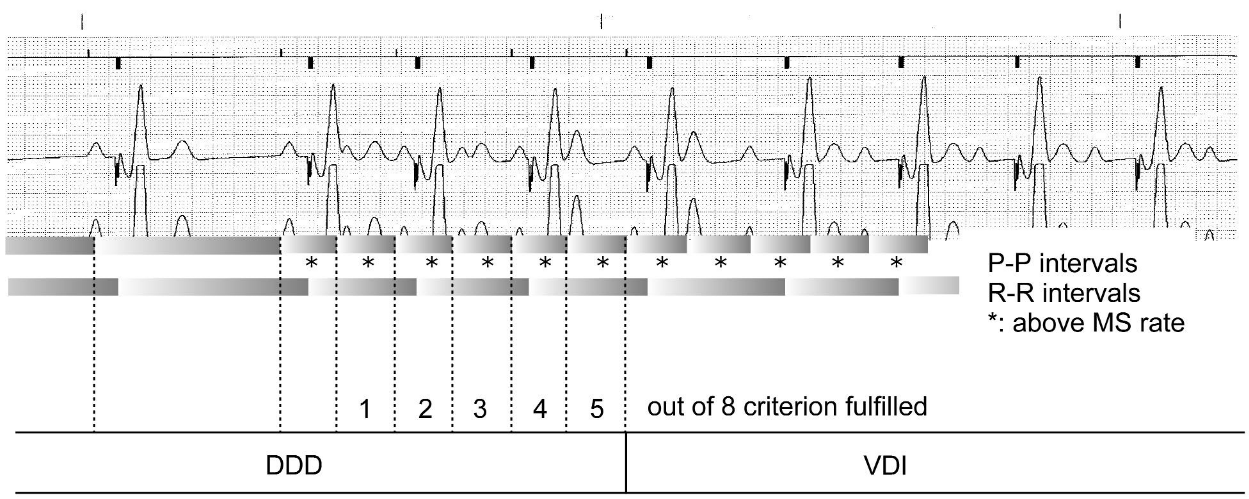

Figure 1. Schematic representation of the "x out of y" criterion for mode-switching. If 5 out of 8 consecutive atrial cycles are shorter than the programmable mode-switching rate (*), the non-tracking mode is activated. The ventricular rate is limited by the URL and the 2:1 point.

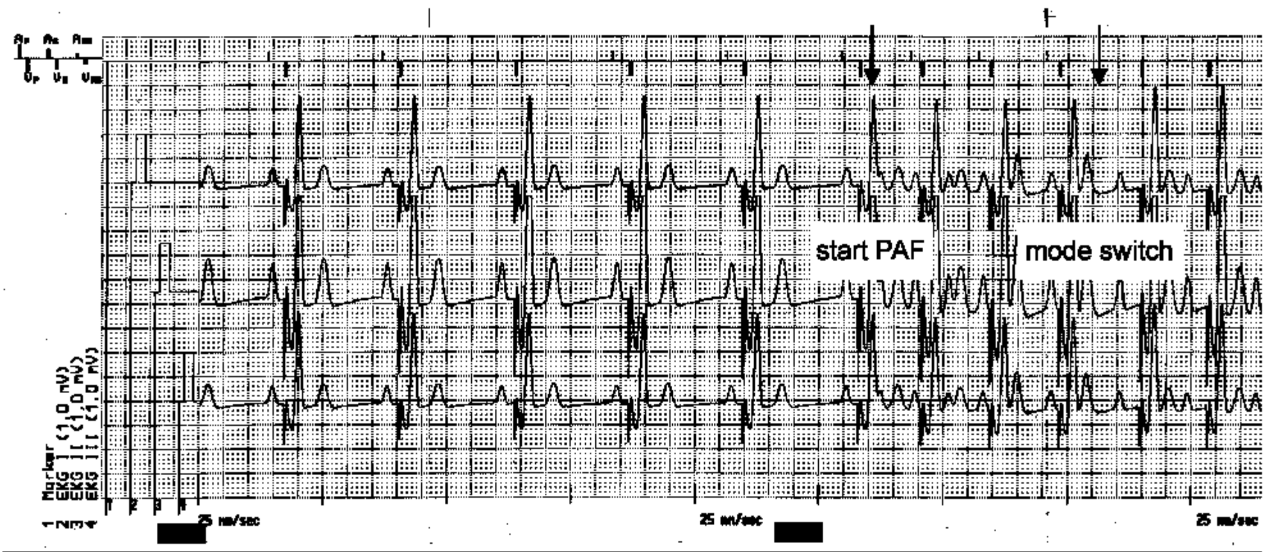

Figure 2. ECG recording during mode-switching. Fast atrial rate is above the mode-switching rate, and the non-tracking mode is activated. VDI rate smoothing maintains a stable ventricular rhythm.

between 80 and 250 bpm for the Logos. Both pacemaker systems switch to non tracking VDI mode (Logos: DDI) during the atrial tachyarrhythmia.

The ventricular rate gradually decreases from the last atrially triggered ventricular interval during sinus rhythm to the lower rate limit (LRL). The beat-to-beat decrease in the ventricular rate is limited to 2 bpm per cycle (for example, from 80 to 78 bpm in one cycle, then 78 to 76 bpm in the next, etc.). When PAF occurs, the ventricular rate decreases from 140 bpm during sinus tachycardia (during exercise, for example) to 60 bpm in 40 sec.

To increase the ability of detecting high atrial rates, only two very short atrial periods are blanked. The atrial blanking periods, during which atrial signals cannot be sensed, are a non-programmable atrial blanking after an atrial paced event (post-atrial atrial blanking, PAAB) of 125 ms and a non-programmable atrial blanking after a ventricular paced event (post-ventricular atrial blanking, PVAB) of 100 ms (35 ms during mode-switching). There is no atrial blanking after an atrial or ventricular sensed event. All atrial sensed events outside these blanking periods-including atrial sensed events in the AV interval after the PAAB and in the post-ventricular refractory period (PVARP) can be used for the mode-switching algorithm. These short atrial blanking times are rendered possible by the use of low-polarization leads (e.g., fractal coated leads) with a good signal-noise-ratio [7] and a high-quality sensing amplifier.

In the Inos pacemaker systems, the device returns to the tracking mode when 8 consecutive atrial events are sensed below the programmed mode-switching rate or are paced. In contrast, Logos pacemakers switch back to tracking mode after "y minus x" atrial events (sensed or paced); "y" is fixed at 8 beats, "x" is identical to the programmed number of atrial events needed for the detection of PAF. In Logos, pacing is performed in the DDI, not the VDI, mode during this confirmation time.

Advantages and Limitations

Reliable mode-switching depends on the algorithm used and the ability of the pacemaker system to sense a high proportion of even small atrial fibrillation signals while the sensing circuit is rejecting far-field signals and myopotentials [8]. Sufficient P-wave sensing during atrial fibrillation with low amplitudes is necessary for adequate mode-switching. In Inos and Logos pacemaker systems, the bipolar atrial sensitivity can be programmed to 0.5 mV, respectively. Thus, atrial undersensing can be avoided, and even very low atrial fibrillation potentials can be reliably detected [9].

In Inos and Logos pacemaker systems, the mode is switched to a non-rate-adaptive mode (VDI or DDI). All pacemaker systems programmed to VDD or VDDR mode will switch to VDI. This may be disadvantageous upon PAF termination, because the lack of atrial stimulation by the pacemaker may cause ventricular pacing of the atrium through retrograde conduction when the atrial arrhythmia stops with a preautomatic sinus pause.

The x out of y criterion used in Inos and Logos pacemakers can reliably switch modes — even during temporary atrial undersensing due to low signal amplitude or an atrial signal during the atrial blanking period — because only 60% of all atrial sense events are necessary for atrial tachycardia detection (e.g., in the Inos, 5 out of 8 atrial events). Short atrial blanking periods and the use of atrial events sensed during normal sensing periods and the atrial refractory period avoid 2:1 tracking (a "lock in") of slow atrial flutter. The "x out of y" algorithm protects the device from inappropriately switching modes due to far-field R-wave oversensing. Far-field R waves must be detected in more than 60% of the cycles in the atrial channel for inappropriate mode-switching to occur; if far-field R-wave oversensing is present in every cycle, the pacemaker will inevitably switch to a non-tracking mode.

The algorithm of the Inos and Logos pacemaker systems does not allow single PACs or couplets and triplets of PACs to trigger mode-switching when the "x" value is programmed to the recommended minimum setting of 4 (in Logos). Still, with atrial rates over 200 bpm, fast mode-switching will occur in 3 s even during slow atrial flutter. In the Logos, programming the "x" value to less than 4 beats (i.e., atrial tachycardia detection when only 2 or 3 atrial events are below the mode-switching detection rate interval) may be disadvantageous, because atrial couplets can trigger a mode-switching episode which will last for at least 8 beats (termination criterion). This tendency to switch modes in reaction to PACs may lead to mode oscillations in patients with frequent PACs or couplets. The same holds true for inappropriate mode-switching due to atrial oversensing: When programming a very "liberal" mode-switching algorithm, frequent oversensing events may easily lead to AV de-synchronization.

Inos^2 CLS returns from the mode-switching operation to the original timing when 8 out of 8 consecutive intervals are longer than the programmed mode-switching detection rate. Therefore, the pacemaker is in an asynchronous mode for the first 7 cycles after the termination of atrial tachycardia. This avoids mode oscillations and secures a stable ventricular rate, but the inability to pace the atrium immediately after the atrial tachyarrhythmia has been stopped may be disadvantageous. The possibility to program the mode-switching detection rate independent of other pacemaker parameters to between 100 and 180 bpm (Inos) and 80 to 250 bpm (Logos), respectively, may facilitate the optimization of the pacemaker system with respect to the type of atrial arrhythmia, intrinsic atrial rhythm, and intrinsic AV conduction.

Recommendations for Programming

1. Atrial Sensing

To better discriminate between atrial potentials and ventricular or muscular potentials, programming a bipolar atrial sensing mode is highly recommended. This is of special importance in a device with increased proportions of atrial sensing during the refractory period (ventricular far-field sensing is not blanked!) when all sensed events may trigger a switch to the non-tracking mode.

The level of atrial sensitivity should be programmed with respect to the sensed P waves; because atrial fibrillation potentials may be considerably lower than P-wave amplitudes, a high atrial sensitivity (0.5 mV) should be programmed in patients with PAF to avoid undersensing of atrial fibrillation with consecutive lack of mode-switching. Additionally, an atrial oversensing test should be performed. During high-voltage pacing in the ventricle, the occurrence of far-field R waves should be evaluated, using telemetry, through the ECG, intraatrial electrogram, and marker annotations. Similarly, myopotential oversensing during arm pressing, etc., should be checked. The highest atrial sensitivity level without evidence of atrial oversensing should be programmed.

2. Mode-Switch Criteria and Rate

In all BIOTRONIK pacemakers, mode-switching is set to "OFF" as a default. If the patient has a history of PAF or it is likely to occur, the "mode-switch" feature should be activated in Inos and Logos devices. The "mode-switching rate" can be programmed, independently of UTL or other parameters, between 100 and 180 bpm (Inos) and 80 and 250 bpm (Logos), respectively, in increments of 10 bpm according to the

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BIOTRONIK PMS 1000

Version    : B-GD0.1.A
Datum/Zeit: 04.12.1998    09:06

INOS2CLS/DR       SN.
Initialisierung     Automatisch

            Atr Frequenztrend
Betriebsart                          DDD
Abfragezeit            04.12.1998 09:04
Mode-Switching                   170 ppm
Aufzeichnungsmode                Rollend
Intervallanzahl                       85

---Ereign. Zeit---     Ereign. Typ
29.10.1998 11:48               Aus
01.11.1998 03:36          Ein
01.11.1998 03:36               Aus
01.11.1998 03:36          Ein
01.11.1998 03:48               Aus
01.11.1998 03:48          Ein
01.11.1998 04:00               Aus
01.11.1998 04:00          Ein
01.11.1998 04:00               Aus
01.11.1998 04:00          Ein
01.11.1999 04:06               Aus
01.11.1998 04:06          Ein
01.11.1998 12:18               Aus
01.11.1998 12:18          Ein
01.11.1998 12:24               Aus
01.11.1998 12:24          Ein
01.11.1998 14:06               Aus
05.11.1998 19:12          Ein
05.11.1998 19:12               Aus
09.11.1998 19:06          Ein
09.11.1998 19:06               Aus
11.11.1998 03:30          Ein
11.11.1998 03:30               Aus
11.11.1998 22:48          Ein
11.11.1998 22:48               Aus
12.11.1998 00:54          Ein
12.11.1998 01:00               Aus
14.11.1998 19:54          Ein
14.11.1998 19:54               Aus
14.11.1998 20:42          Ein
14.11.1998 20:42               Aus
14.11.1998 20:42          Ein
14.11.1998 20:42               Aus
16.11.1998 12:36          Ein
16.11.1998 12:36               Aus
17.11.1998 11:36          Ein
17.11.1998 11:36               Aus
18.11.1998 05:30          Ein
18.11.1998 06:54               Aus
18.11.1998 05:54          Ein
18.11.1998 07:06               Aus
18.11.1998 07:06          Ein
18.11.1998 12:18               Aus
19.11.1998 17:06          Ein
19.11.1998 17:06               Aus
20.11.1998 11:36          Ein
20.11.1998 11:36               Aus
21.11.1998 12:24          Ein
21.11.1998 12:24               Aus
21.11.1998 16:12          Ein
21.11.1998 16:12               Aus
22.11.1998 02:48          Ein
22.11.1998 02:48               Aus
22.11.1998 02:48          Ein
22.11.1998 02:48               Aus
22.11.1998 13:06          Ein
22.11.1998 13:06               Aus
24.11.1998 00:36          Ein
24.11.1998 10:30               Aus
27.11.1998 13:18          Ein
27.11.1998 13:18               Aus
27.11.1998 13:30          Ein
27.11.1998 13:30               Aus
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27.11.1998 13:30          Ein
27.11.1998 13:30               Aus
27.11.1998 13:42          Ein
27.11.1998 13:42               Aus
27.11.1998 13:42          Ein
27.11.1998 13:42               Aus
27.11.1998 14:06          Ein
27.11.1998 14:06               Aus
28.11.1998 12:54          Ein
28.11.1998 21:06               Aus
28.11.1998 21:06          Ein
28.11.1998 23:54               Aus
28.11.1998 23:54          Ein
29.11.1998 00:48               Aus
02.12.1998 12:54          Ein
02.12.1998 12:54               Aus
02.12.1998 13:00          Ein
02.12.1998 13:00               Aus
Datenende
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Figure 3a. Programmer printout of mode-switching statistics of the Inos[2] CLS. Data document date and time of each mode-switching activation and termination with a pacemaker clock of six minutes. The number and the duration of each mode-switching episode, as well as the distribution of mode-switching events in respect to circadian rhythm, can be evaluated.

patient's atrial arrhythmia. The detection rate is not coupled to the total atrial refractory period (TARP) as in BIOTRONIK pacemakers with the "mode conversion" feature (Actros and Kairos) and can be programmed independently of the AV interval and PVARP.

The "x out of y" criterion is programmable in the Logos systems (4 is the default value for x, which is programmable between 2 and 7; y is fixed to 8). In patients with a high percentage of undersensed atrial fibrillation, programming "x" to 3 beats may be helpful in the case of a symptomatic lack of mode-switching during atrial fibrillation. Still, a too liberal programming of the decision criteria may lead to inappropriate mode-switching and mode oscillations. A more restrictive criterion may help to avoid inappropriate mode-switching due to far-field R-wave oversensing; but it may lead to a lack of mode-switching during PAF and cause mode oscillations if termination criteria are met too soon. In the Inos, the "x out of y" criterion is fixed to 5 out of 8 beats.

3. Upper and Lower Rate Limits (LRL), Sensor Rate, Rate Smoothing

In the Inos and Logos systems, the mode-switching function may be programmed independently of UTL, LRL, maximal sensor rate and maximal closed loop rate (MCLR). The LRL is important (even in the DDD-CLS mode) for pacing during PAF in the Inos and Logos, because the ventricular rate will be decreased to the programmed LRL. Rate smoothing is not programmable (decrease by 2 bpm per cycle). The MCLR programming bears importance for the rate after the conversion to sinus rhythm in the Inos (a switch from VDI to DDD-CLS).

4. Atrial Blanking and Refractory Periods

In all the systems discussed in this paper, the sensing portions of the total atrial refractory period (TARP) are enlarged by including parts of the AV interval. Only the first 125 ms after an atrial paced event are blanked, the rest of the AV interval is only refractory and events sensed during this period are used for atrial tachycardia detection. Similarly, only the first 100 ms (during mode-switching: 35 ms) after a ventricular paced event are blanked, and the rest of the PVARP is able to detect atrial sensed events. In Logos, the PVARP depends on the AV interval and TARP programming (e.g., with the default settings of the AV interval being 180 ms and the TARP 450 ms, the PVARP is 270 ms). In the Inos,

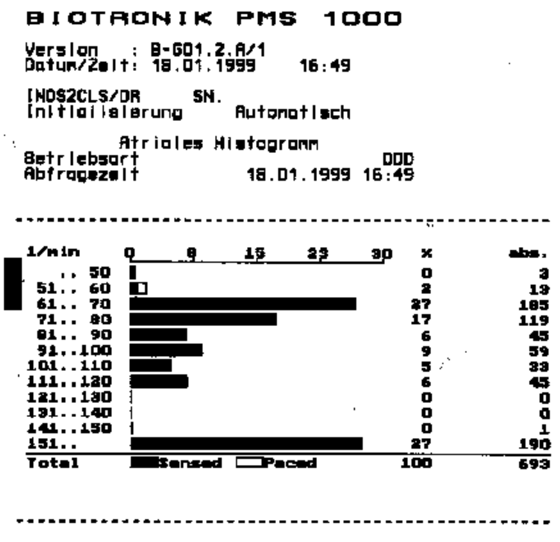


Figure 3b. Atrial rate histogram. In addition to the distribution of atrial rates during sinus rhythm, the ratio during the PAF episodes can be evaluated.

the AV interval and PVARP are programmable and determine the TARP. Still, the refractory periods are important for determining 2:1 block rather than mode-switching function.

Diagnostic Functions

The diagnostic functions facilitate optimization of pacing therapy during PAF. Therefore, Inos² CLS and Logos pacemakers automatically start recording mode-switching statistics when mode-switching is activated. The date and time of every onset and offset of the last 42 mode-switch operations are stored. Thus, the total number of mode-switching events, the duration of each event, the total time in non-tracking mode (presumably due to PAF) within the follow-up period, and the time of day when mode-switching occurred can be evaluated (see Figure 3a). In addition, the atrial rate histogram allows the rate of atrial arrhythmias to be estimated (< 150 bpm or > 151 bpm, see Figure 3b) and may confirm the percentage of high atrial rates as estimated from the numerical statistical analysis (Figure 3a). Presently, only the Inos² CLS software for suppressing PAF through overdrive stimulation (DDD⁺ mode) allows the additional storage of single episodes of high atrial rates during PAF with stored marker sequences of the last cycles before and the first cycles after the onset of mode-switching (Figure 4; default settings 10 cycles before and 5 cycles after mode-switching; programmable).

An example of the benefits of diagnostic data is illustrated in Figure 5. After AV node ablation because of

Non-AF Event and Intervalhistory

Rec	Interval (ms)	Rate (bpm)	As	Ap	Vs	Vp	Ars	PVC	PAC	SWV
0	600.6	99.9	X	-	-	X	-	-	-	-
1	600.6	99.9	X	-	-	X	-	-	-	-
2	592.8	101.2	X	-	-	X	-	-	-	-
3	592.8	101.2	X	-	-	X	-	-	-	-
4	592.8	101.2	X	-	-	X	-	-	-	-
5	374.4	160.25	X	-	-	X	-	-	-	-
6	382.2	156.98	X	-	-	X	-	-	X	-
7	382.2	156.98	X	-	-	X	-	-	X	-
8	382.2	156.98	X	-	-	X	-	-	-	-
9	374.4	160.25	X	-	-	X	-	-	-	-

AF Event and Intervalhistory

Rec	Interval (ms)	Rate (bpm)	As	Ap	Vs	Vp	Ars	PVC	PAC	SWV
0	288.6	207.9	X	-	-	X	-	-	-	-
1	374.4	160.25	-	-	-	X	X	-	-	-
2	374.4	160.25	-	-	-	X	X	-	-	-
3	382.2	156.98	-	-	-	X	X	-	-	-
4	374.4	160.25	-	-	-	X	X	-	-	-

Figure 4. Mode-switch episode. A marker-IEGM of the last 10 cycles before mode-switching and of the first 5 cycles in the VDI mode is stored. This enables the validation of every mode-switching activation.

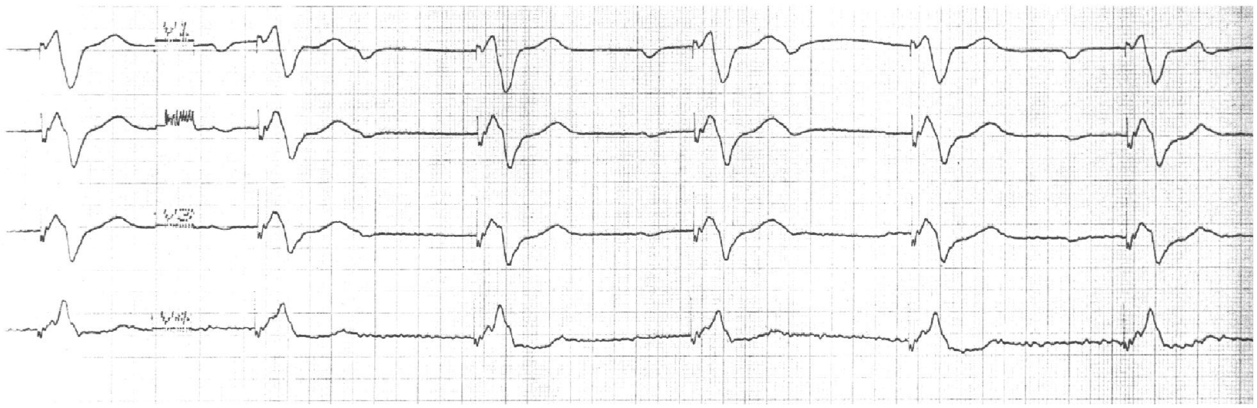


Figure 5a. ECG recording demonstrating asynchronous ventricular pacing in a patient with an Inos device; visible P waves rule out atrial flutter or fibrillation.

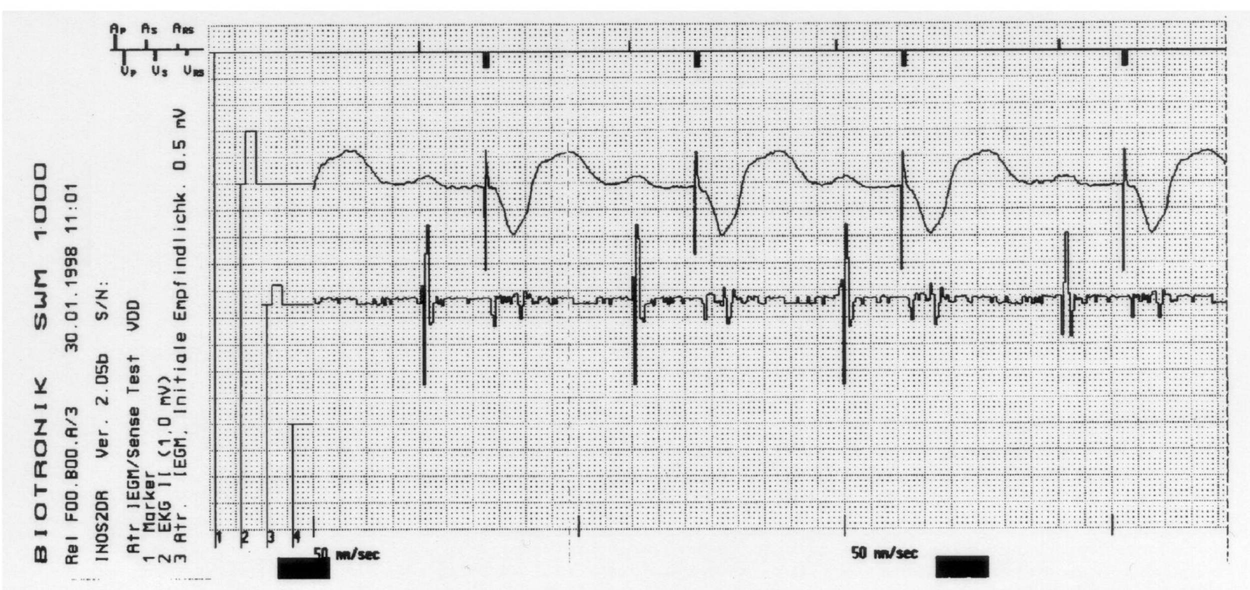
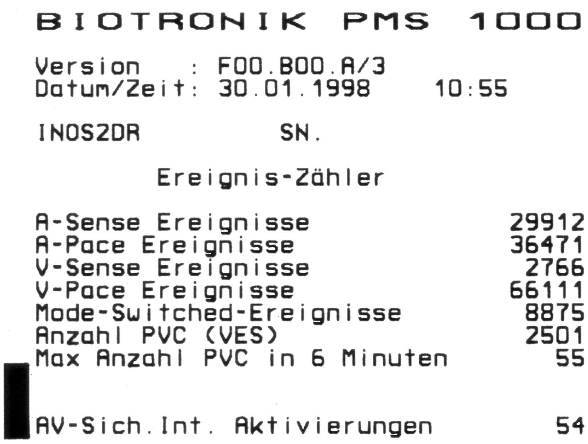


Figure 5b. The intracardiac ECG recording confirms two ventricular far-field signals sensed in the atrial sensing channel after each ventricular pace. Re-programming atrial sensitivity to 1.0 mV prevents far-field R-wave oversensing and establishes proper mode-switching behavior.

drug-refractory paroxysmal atrial fibrillation with tachyarrhythmic conduction and resulting ventricular rates between 110 and 160 bpm, a patient with congestive heart failure was implanted with an Inos[2] CLS pacemaker. At discharge, the pacemaker was programmed to the DDD mode, the rate for triggering the mode switch was set to 160 bpm. Atrial sensitivity was set to 0.5 mV with bipolar atrial sensing polarity. At the 6-week follow-up visit, an ECG was recorded showing asynchronous ventricular pacing (Figure 5a). Using the intracardiac electrocardiogram (Figure 5b) and stored statistical data (Figures 5c and d), it was confirmed that mode-switching was active due to oversensing of far-field R waves. Reprogramming the atri-



BIOTRONIK PMS 1000

Version : F00.B00.A/3
Datum/Zeit: 30.01.1998 10:55

INOS2DR SN.

Ereignis-Zähler

A-Sense Ereignisse	29912
A-Pace Ereignisse	36471
V-Sense Ereignisse	2766
V-Pace Ereignisse	66111
Mode-Switched-Ereignisse	8875
Anzahl PVC (VES)	2501
Max Anzahl PVC in 6 Minuten	55
AV-Sich.Int. Aktivierungen	54

Figure 5c. Print out of the counter statistic of the pacemaker. The high number of mode-switch events (n=8875) indicates that impaired sensing behaviour (e.g. oversensing) may lead to inappropriate mode-switching.

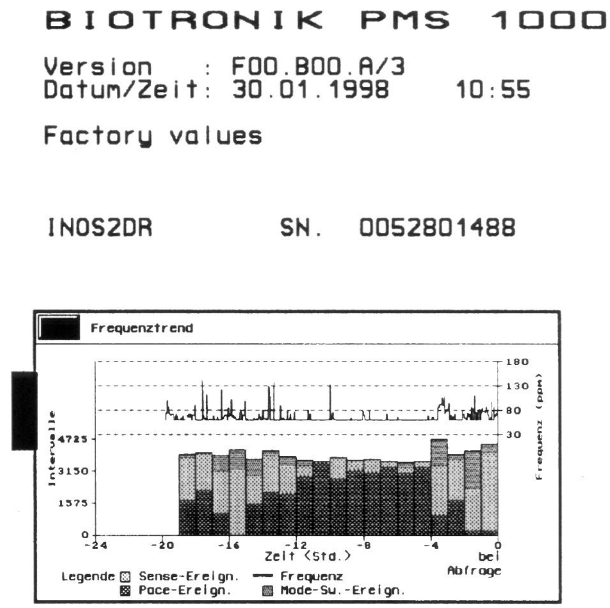


Figure 5d. Rate trend of the pacemaker. Also this statistic confirms the counter statistic that inappropriate mode-switching occured.

al sensitivity to 1.0 mV resolved the problem of sensing far-field R waves, and AV-synchronous pacing was restored.

Conclusion

The "x out of y" criterion of the Inos² CLS and Logos pacemaker systems provides a higher specificity than algorithms with a beat-to-beat mode-switching and a faster reaction than PAF detection algorithms that use mean atrial rates. Activating the mode-switching in these devices requires setting only one parameter, the detection rate, thus avoiding complex programming steps. The far-field R-wave test, using the telemetric feature for simultaneous ECG, intraatrial and intraventricular electrograms and marker annotations, provides a fast and easy possibility to evaluate pacemaker performance during follow-up tests.

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Table of Abbreviations

Abbreviation	English	German
AVI	atrio-ventricular interval	AV Intervall
CLS	Closed Loop Stimulation	Closed Loop Stimulation
CMRR	common mode rejection ratio	Gleichtaktunterdrückung
FFRW	far-field R wave	Fernfeld der R-Welle
IEGM	intracardiac electrogram	Intrakardiales EKG
LRL	lower rate limit	Grundfrequenz
MCLR	maximum closed loop rate	maximale Closed Loop Frequenz
MS	mode-switch	Mode-Switch
PAC	premature atrial contraction	atriale Extrasystole
PAF	paroxysmal atrial fibrillation/ atrial flutter	paroxysmales Vorhofflimmern/ Vorhoffflattern
PAAB	post-atrial atrial blanking (atrial blanking following atrial stimulation)	postatriales atriales Blanking (atriales Blanking nach einer atrialen Stimulation)
PVAB	post-ventricular atrial blanking (atrial blanking following ventricular stimulation)	postventrikuläres atriales Blanking (atriales Blanking nach einer ventrikulären Stimulation)
PVARP	post-ventricular atrial refractory period	postventrikuläre atriale Refraktär-zeit