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Dr S. GARRIGUE - Dr S. REUTER
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Defibrillators
Saint Jude Medical
New recommendations
Algorithm SecureSense™

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Avenue Ariane
Parc Cadera Sud BAT P1 LOT 18
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Email : contact@stimuprat.com

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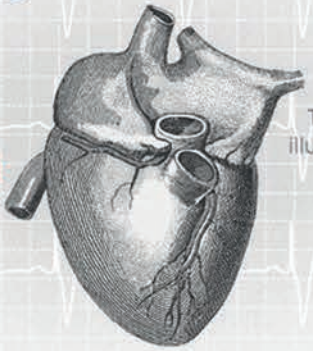

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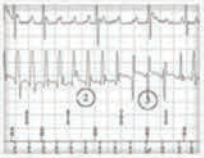

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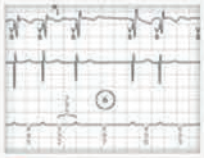

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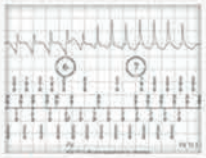

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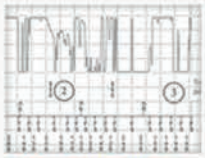

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Sommaire

Introduction

The efficacy of implantable defibrillators (ICD) in the prevention of sudden death has been confirmed by multiple studies and countless patients. This efficacy, however, depends on the device programming, which varies considerably among medical centers and, within a single center, among the various caregivers. While the different settings may need to be optimized according to the characteristics of each device recipient, such as age, type of heart disease, or primary versus secondary prevention, some general programming rules apply to a majority. A recent article published in Heart Rhythm Journal, written by representatives of the Heart Rhythm Society, European Heart Rhythm Association, Asian Pacific Heart Rhythm Society and Sociedad Latino-Americana of Estimulacion Cardiaca y Electrofisiologia, discusses in depth the data pertaining to 4 important areas of ICD programming, including 1) pacing parameters, 2) sensing and programming zones, 3) programming of shocks and antitachycardia pacing (ATP), and 4) induction of a ventricular arrhythmia at the end of the implantation procedure. They formulated 32 guidelines (class I, IIA, IIB and III) with evidence levels that vary as a function of the number and type of publications (A, B or C). The main document includes an addendum which offers specific recommendations for the programming of the devices made by the 5 main manufacturers.

This monograph reviews the main guidelines pertaining to the programming of ICD manufactured by St. Jude Medical, Inc., illustrated by representative tracings highlighting, in particular, the specific characteristics and advantages of the SecureSense™ algorithm included in the most recent devices made by this manufacturer.

Parts of this monograph are available in French and English on the Internet site <pacingdefibrillation.com>. This freely accessible site reviews the field's state of the art, going into the details of the specific features of the various pacing, defibrillating and resynchronizing devices. It might also promote exchanges of ideas in discussion forums, enabling the posting of tracings followed by debates on the optimal diagnosis and therapeutic choices.

Enjoy the reading!

Chapter 1

Programming the Saint Jude Medical Defibrillators

Programming the St. Jude Medical defibrillators: latest guidelines

Programming an ICD is complex and must merge the characteristics of the device recipient with the specific ways the various devices detect, count and discriminate. It may be, at times, challenging to extrapolate the results of a study that used the ICD of a manufacturer to the devices of the 4 competitors, given the fundamental differences in their conception and function. In absence of an optimal, universal programming, the results of large studies are concordant with regard to the need to a) limit the incidence of inappropriate or unnecessary therapies, without jeopardizing the patient's safety, and b) give priority to ATP instead of electric shocks, which might improve the quality of life as well as increase survival. The formulation of guidelines to outline the programming principles of ICD became necessary to standardize the practices of the various implanting medical centers. It is based on a detailed analysis of the literature in order to define the broad rules of programming, as well as describe the different standard programming of the devices made by the 5 main manufacturers. It is noteworthy that the proposed programming is often markedly different from the nominal programming recommended by the manufacturers.

Anti-bradycardia programming

In St. Jude Medical defibrillators and in absence of indication for ventricular pacing, the programming recommendation is VVI at 40 bpm for single chamber devices, and DDD with the VIP algorithm ON to promote spontaneous atrioventricular conduction for dual chamber devices. The aim, in this instance (class I indication) is to eliminate unnecessary and deleterious right ventricular (RV) pacing, known to increase mortality and rates of hospitalization.

Patients presenting with sinus node dysfunction must receive dual chamber (class I indication) instead of single chamber ICD with a view to improve the quality of life and lower the risk of pacemaker syndrome, atrial fibrillation and cerebral vascular accidents.

In recipients of triple chamber defibrillator, the device programming must enable a percentage of biventricular stimulation approaching 100%, with the QuickOpt™ algorithm programmed ON, which automatically adjusts the atrioventricular delay and interventricular delays despite the absence of a formal confirmation of its efficacy.

Detection

For a primary prevention indication, a 30-cycle ventricular tachycardia (VT) zone between 187 and 250 bpm and a 30-cycle ventricular fibrillation (VF) zone >250 bpm must be programmed. For a secondary prevention indication, these 2 zones may be supplemented by an additional VT zone 10 to 20 bpm slower than the clinical VT. These programming guidelines correspond to those formulated in the main document:

1) In primary or secondary prevention, whether in the VT or VF zone, the device programming must allow a minimum duration of 6 seconds (or approximately 30 cycles depending on the rate) before the detection counter is full, to limit the overall number of appropriate or inappropriate therapies delivered (class I indication)

2) In primary prevention, the slowest zone of therapy must be programmed between 185 and 200 bpm to limit the overall number of therapies delivered (class I indication)

3) In secondary prevention, when the cycle of the clinical VT is known, a VT zone 10 à 20 bpm slower than that tachycardia should be programmed (class IIA indication).

In the early days, the programming priority of ICD was a rapid detection and treatment of ventricular arrhythmias because of several considerations: a) most patients underwent implantation of the device for a secondary prevention indication after reanimation from cardiac arrest, b) the charge time of monophasic shocks could exceed 10 seconds, c) the energy required to defibrillate increased with the duration of the tachyarrhythmia, and d) a risk of undersensing of the ventricular EGM also increased with the length of the tachyarrhythmia. Furthermore, depending on the practices at the various implanting medical centers, the tachycardia zones could be programmed relatively slow with the intent to treat all clinical ventricular tachyarrhythmias.

Along with the evolution of the technology and the changes in indications (higher prevalence of

implants for primary prevention indications), various large studies showed that the programming of an excessively short delay between the onset of tachyarrhythmia and the first therapy delivery or of excessively slow zones of tachycardia increased the risk of inappropriate as well as unnecessary therapies delivered for episodes of ventricular tachycardia (VT), which would have ended spontaneously, had a greater number of cycles been programmed.
The MADIT RIT study, in recipients of Boston Scientific defibrillators implanted for primary prevention indications, revealed that the programming of a very short VT detection zone starting at 170 bpm was likely to increase significantly the risk of appropriate though avoidable therapies, the number of inappropriate therapies, and the rate of hospitalizations and mortality. Other studies have also shown that the programming of a prolonged duration or a greater number (30/40) of cycles needed to fill the VF counter, lowered the overall number of therapies delivered without increasing significantly the risk of syncope.
The PROVIDE study, in 1,670 recipients of St. Jude Medical ICD implanted for primary prevention indications, compared a group of patients whose device was programmed in the usual fashion (cycles limited to 12 in a single VT zone and 12 in the VF zone) versus a group with the programming of a) 25 cycles between 180 and 214 bpm (VT zone 1), b) 18 cycles between 214 and 250 bpm (VT zone 2), and c) 12 cycles >250 bpm (VF zone). In the second group, the overall number of shocks and mortality were significantly lowered, emphasizing the foremost importance of the programming of these settings, and imposing an unequivocal change in the programming routine.
The programming recommended for the St. Jude Medical ICD is not simply based on the results of that last study and includes the observation of a significant improvement in the prognosis and survival of ICD recipients by the programming of a large number of cycles, including in the VF zone. The 30 cycles recommended in the VT or VF zones is greater than the 12 cycles used in the PROVIDE study. Likewise, this number of cycles and the limit of the VF zone are far superior to the nominal values recommended by St. Jude Medical.

Therapies

In the VF zone, the programming of a) an ATP sequence (burst, 85%) during/before the charge and of b) the highest shock amplitude is recommended. In the VT2 zone, ≥1 burst of ATP (85%) must be programmed. And in the VT1 zone (secondary prevention indication), ATP must also be programmed.
This programming scheme is concordant with the guidelines formulated in the main document:
1) In all patients presenting with structural heart disease who are at risk of developing an organized VT, ≥1 sequence of ATP should be programmed (unless it is known to be unsuccessful or arrhythmogenic) in the zones of VT and VF with a view to obviate the need to deliver an electric shock (class I indication).
2) A burst of ≥8 stimuli instead of a ramp (class I indication) and a cycle length between 84 and 88% of the tachycardia cycle length (class I indication) should be programmed.
Recent studies have observed that, while the delivery of an electric shock is the only effective means of terminating a very rapid polymorphous ventricular tachyarrhythmia, the need to deliver ≥1 electric shocks to terminate an organized ventricular arrhythmia, regardless of its rate and zone (VT or VF), is associated with a significant degradation of the prognosis. The choice of ATP instead of a shock for this type of arrhythmia is, therefore, a programming priority (class I indication) that improves the quality of life, and lowers the power consumption as well as mortality. The efficacy of bursts seems greater than that of ramps (PITAGORA study) with a more favorable arrhythmia termination / acceleration to polymorphous arrhythmia ratio. While a single burst can usually be programmed in the VF zone, the number of bursts that must be programmed in the VT zone is debatable, though the delivery of >3 bursts is rarely successful.

Discrimination

In the case of St. Jude Medical single chamber ICD, it is recommended to limit the programming to the settings based on the morphology analysis (sudden onset and stability set on "Passive"). In the case of dual or triple chamber ICD, all the discrimination settings, including morphology, stability and onset must be programmed ON, since the diagnosis of VT requires that they all be satisfied. Discrimination must be effective to a ≥230 bpm limit. This programming recommendation

corresponds to those formulated in the main document:
1) Except in patients who present with an abnormal atrioventricular conduction, the discrimination algorithms must be programmed to a rate of 230 bpm to limit the risk of inappropriate therapy (class I indication).
2) It is recommended to turn off the clocks (time-out) that force the delivery of therapies beyond a set duration, including when the device diagnoses an SVT (class IIB indication).
The combination of a) relatively high programming of tachycardia zones, b) counters requiring a large number (30) of cycles, and c) reliable VT/SVT discrimination algorithms up to 200 to 230 bpm has considerably decreased the incidence of inappropriate therapies. The need to discriminate the origin of tachycardias is highest in patients at risk of overlap between the VT and SVT rates, i.e. patients presenting with slow VT and episodes of atrial fibrillation with a rapid ventricular response or with sinus tachycardia. Conversely, the discrimination algorithms must be turned off in patients presenting with complete atrioventricular block. With the devices made by St. Jude Medical, the discrimination is only possible within the VT zones and impossible in the VF zone. Therefore, the choice of lower limit of the VF zone has a major effect on the discrimination of arrhythmias, explaining in part the recommendation of programming a VF zone starting at 250 bpm. A 230-bpm limit has been recommended to implement this discrimination, after the observation, in some patients, of rates >200 bpm during episodes of AF, and to not discriminate tachyarrhythmias whose rates are >230 bpm, since faster SVT are rare and since the risk of misclassification of ventricular arrhythmias is high.

Tracing 1: counters and therapies in the VT zone

Patient

This 67-year-old man received a St. Jude Medical Ellipse™ VR defibrillator for the management of advanced ischemic cardiomyopathy complicated by repetitive episodes of non-sustained (NS) VT. He was seen for evaluation of syncope and delivery of an electric shock.

Tracing 1A

1: sinus rhythm; cycles classified VS;
2: sudden onset of a regular monomorphous tachycardia, with change in morphology; probable VT; initial cycles classified (-) because of discordance between the instantaneous (fast) and average of the 4 previous cycles (slow);
3: first cycle classified T (concordance between instantaneous and averaged cycles);
4: after 6 T classified cycles, episode recorded in the electrogram (EGM) memories (NSVT);
5: spontaneous termination after 7 T classified cycles; the VT counter was not filled;

Tracing 1B

1: similar episode;
2: spontaneous termination after 13 T classified cycles (a few cycles before filling of the VT counter);

Tracing 1C

1: similar episode;
2: after 16 T classified cycles, the VT counter is filled;
3: first therapy corresponding to the VT zone; it is a ramp;
4: subtle acceleration of the ventricular rate followed by termination;

Tracing 1D

1: similar episode;
2: after 16 T classified cycles, the VT counter is full;
3: first therapy corresponding to the VT zone; it is a ramp (pacing with cycles shortening from 252 to 200 ms);
4: instead of termination, the ventricular rhythm is markedly accelerated, detected in the VF zone and becomes polymorphous;
5: after 12 F classified cycles, an episode of VF is detected; the capacitors begin to charge;
6: end of charge and delivery of 30 J shock;
7: end of arrhythmia and return to sinus rhythm diagnosed;

Comments

These tracings highlight 2 critical points of ICD programming:
- this patient had undergone device implantation in the context of ischemic cardiomyopathy with multiple episodes of asymptomatic or nearly asymptomatic NSVT (4 to 20 cycles). He never experienced an episode of sustained VT or of syncope before the implantation. Not long thereafter, he presented after loss of consciousness and electric shock in absence of apparent triggering factor. Interrogation of the memories revealed many episodes of NSVT, as well as a few episodes treated by ATP and a single episode treated by a shock. Further scrutiny of the tracing revealed a proarrhythmic effect of the ramp and acceleration of stable VT to a rapid, polymorphous ventricular arrhythmia causing syncope and terminated by a life-saving electric shock. It seems highly likely that this episode was due to a poorly chosen programming. The priority in the management of these episodes of NSVT was to promote their spontaneous termination, and to program a sufficient number of cycles to avoid this undesirable outcome. Acceleration of an arrhythmia is an immediate risk, should its treatment with a shock be unsuccessful, as well as prognostically unfavorable on the long-term, since the survival

of patients is jeopardized by the delivery of multiple electric shocks. The device programming was, therefore, modified by an increase in the number of cycles needed to fill the counters, from 16 to 30 in the VT, and from 12 to 30 in the VF zones. This should offer a wide enough margin and promote a spontaneous termination without increasing significantly the risk of syncope, should the tachyarrhythmia be sustained, keeping in mind that, in the updated professional guidelines, it is now a class I indication.

- these tracings underscore another important point with regard to the choice of programming of the type of ATP sequence. The first therapy in the VT zone was a ramp, which may be surprising and against the latest guidelines, which clearly favor the programming of bursts (recommendation class I level), apparently more effective from the standpoint of the terminations / accelerations ratio. Furthermore, the coupling and the decrement of that ramp were probably both excessively aggressive, since the last pulse was delivered at the shortest coupling interval of 200 ms. The programming was replaced by 3 bursts, followed by the highest amplitude shocks in the VT zone.

ST. JUDE MEDICAL

3 Jun 2016
11:25
Archive

Episode: Non-sustained (174 bpm / 343 ms)

26 Jun 2015 14:31

Duration	00:04 (M:S)	**No Alerts**
Zone nearest detection:	VT	

Therapy	**Results**
No therapies were delivered	

ST. JUDE MEDICAL

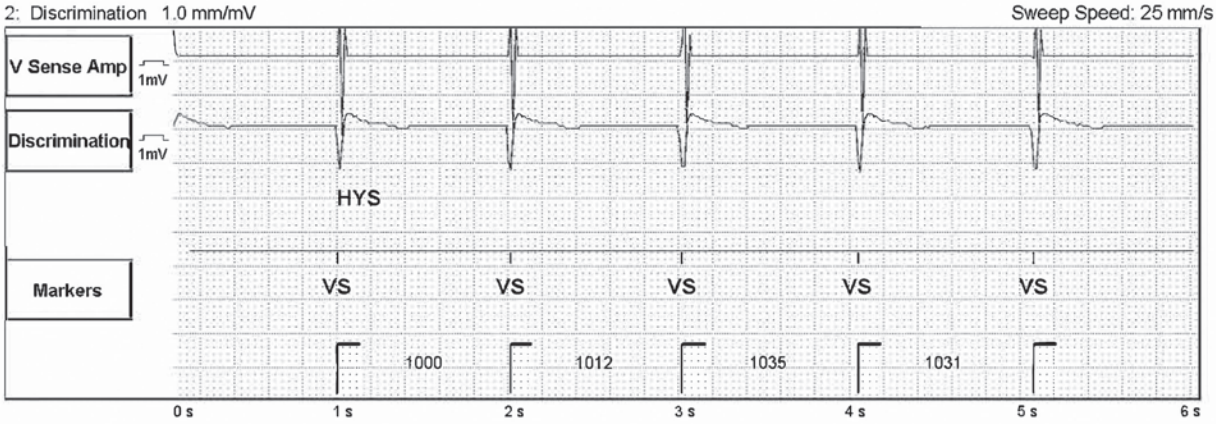
3 Jun 2016
11:25
Archive

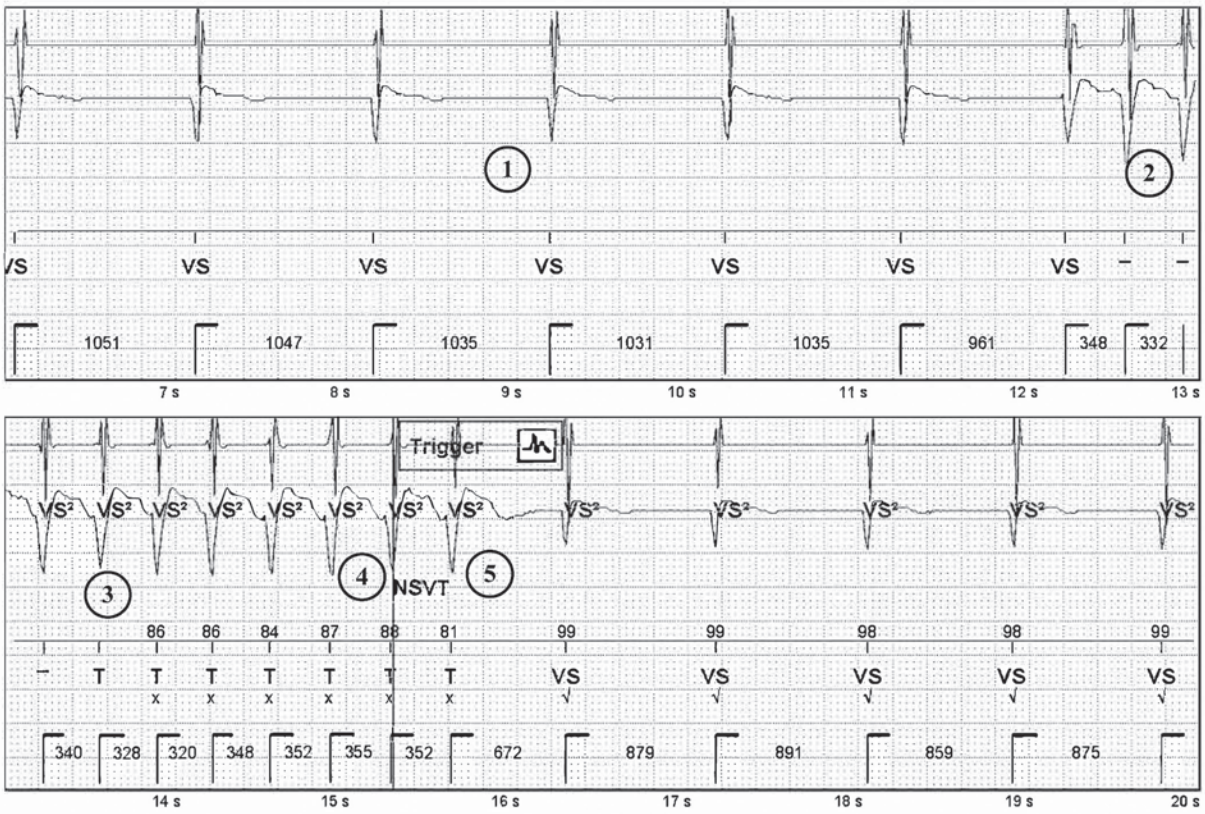
Episode: Non-sustained (174 bpm / 343 ms)

VT/VF Episode 9 of 10
Page 2 of 3

26 Jun 2015 14:31

1: V Sense Amp 1.0 mm/mV
2: Discrimination 1.0 mm/mV
3: Markers
Sweep Speed: 25 mm/s





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Episode: Non-sustained (174 bpm / 343 ms) (Continued)

VT/VF Episode 9 of 10
Page 3 of 3

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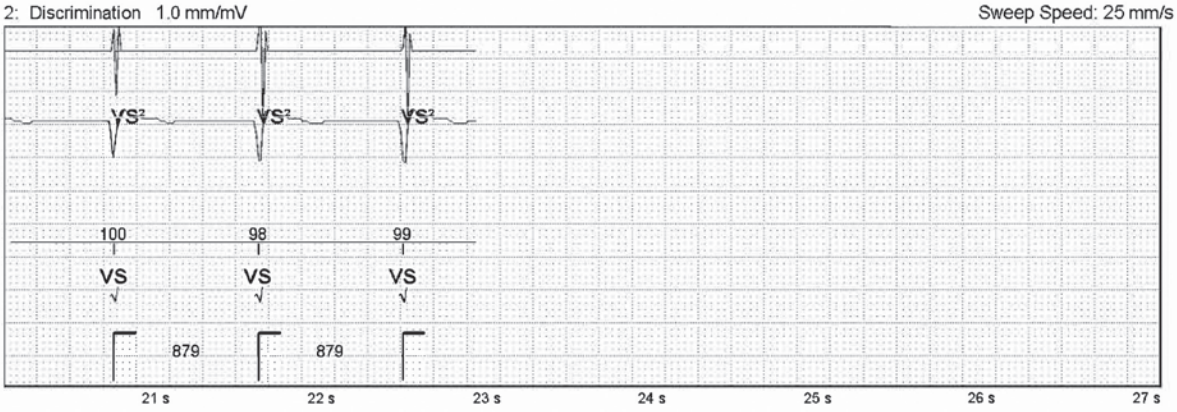

ST. JUDE MEDICAL

3 Jun 2016
11:25
Archive

Episode: Non-sustained (170 bpm / 351 ms)

5 May 2016 6:08

Duration	00:08 (M:S)	**No Alerts**
Zone nearest detection:	VT	

Therapy	**Results**
No therapies were delivered	

ST. JUDE MEDICAL

3 Jun 2016
11:25
Archive

Episode: Non-sustained (170 bpm / 351 ms)

VT/VF Episode 10 of 10
Page 2 of 3

5 May 2016 6:08

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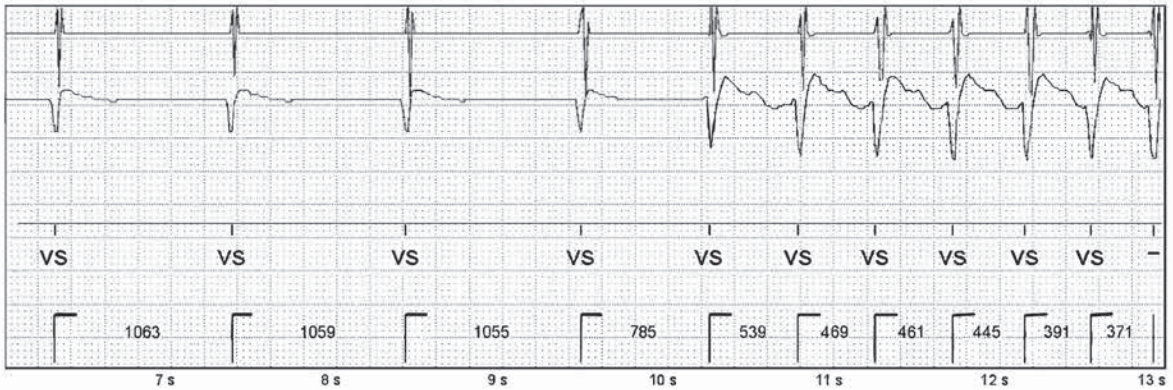

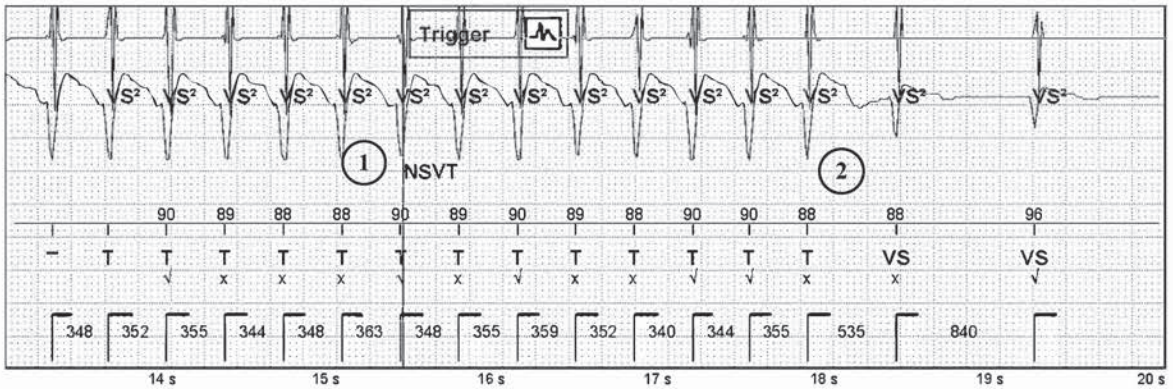

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3 Jun 2016
11:25
Archive

Episode: Non-sustained (170 bpm / 351 ms) (Continued)

VT/VF Episode 10 of 10
Page 3 of 3

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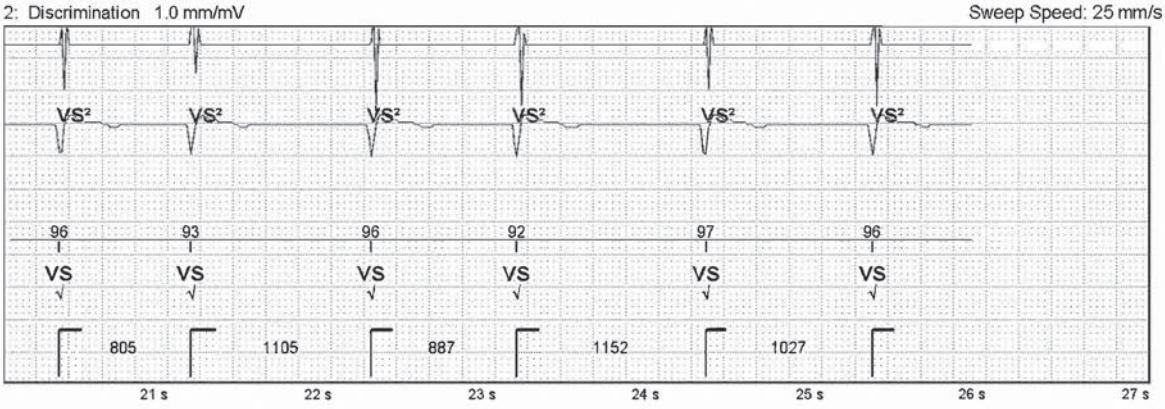

ST. JUDE MEDICAL

3 Jun 2016
11:25
Archive

Episode: VT (193 bpm / 310 ms)

VT/VF Episode 4 of 10
Page 1 of 3

15 Mar 2015 8:24

Duration	00:10 (M:S)	**No Alerts**
Detection Criteria	162 - 213 bpm	

Therapy	**Results**
1) ATP	1) Below Rate Detection (CL 635 ms)

ATP Therapy Details
VT ATP Therapy

Successful BCL 248 ms
Therapy 1
* Burst 1 248, 238, 228, 218, 208, 200, 200 ms

*Min BCL reached in burst

Diagnosis Summary

	Diagnosis
	VT
Time to Diagnosis	4.50 sec
Rate (CL)	193 bpm (310 ms)
Zone	VT
VT Diagnosis Criteria	2 of 3
Morphology	On, ≥ 90% is a match, ≥ 3 matches indicate SVT
Min Match Score	n/a
Max Non-Match Score	65%
No. Template Matches	0 of 10 **(VT Indicated)**
Sudden Onset	On, < 20 % indicates SVT
Max Delta	66 % **(VT Indicated)**
Interval Stability	On w/SIH, ≥ 40 ms or SIH Count ≥ 2 intervals indicates SVT
Stability Delta	10 ms
SIH Count	0 **(VT Indicated)**

SVT Criteria Statistics
SVT Diagnoses during this episode 0

Measured SVT Discriminator values through initial VT/VF Diagnosis

Min Match Score	n/a	Min/Max Stability Delta	10 ms /10 ms
Max Non-Match Score	65 %	Min/Max SIH Count	0 / 0
Template Used	15 Mar 2015 6:38	Max Onset Delta	66 %

DeFT Response™ Settings (Shock Waveform)			**1st Phase**	**2nd Phase**
Waveform	Biphasic	VF Shocks (Defib)	65 %	65 %
Waveform Mode	Tilt	VT Shocks (CVRT)	Same as Defib	Same as Defib
Shock Configuration	RV to Can			
RV Polarity	Anode(+)			
Defib Max Sensitivity	0.5 mV			

ST. JUDE MEDICAL

3 Jun 2016
11:25
Archive

Episode: VT (193 bpm / 310 ms)

15 Mar 2015 8:24

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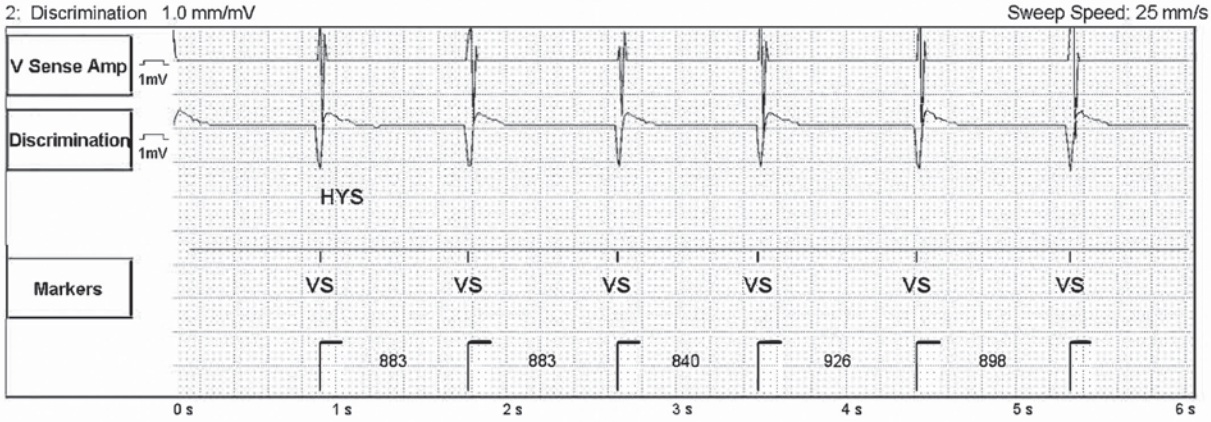
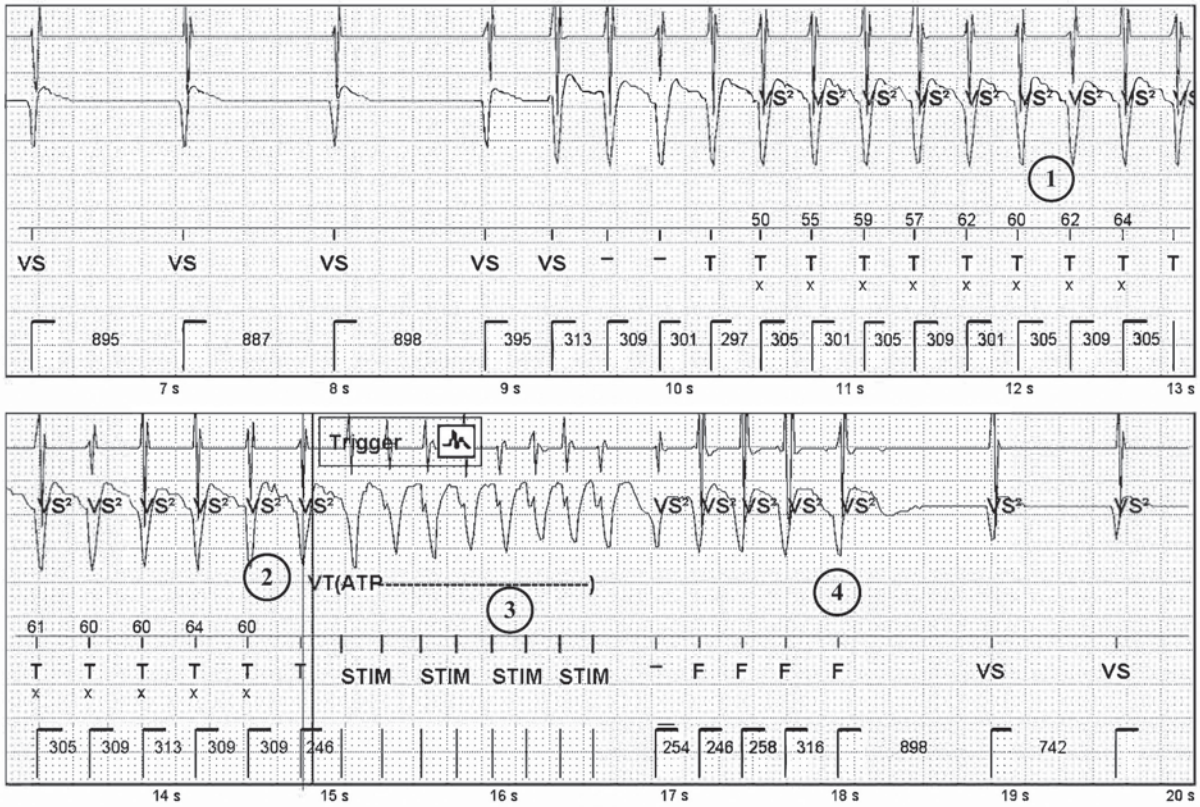
3: Markers

Sweep Speed: 25 mm/s





ST. JUDE MEDICAL

3 Jun 2016
11:25
Archive

Episode: VT (193 bpm / 310 ms) (Continued)

VT/VF Episode 4 of 10
Page 3 of 3

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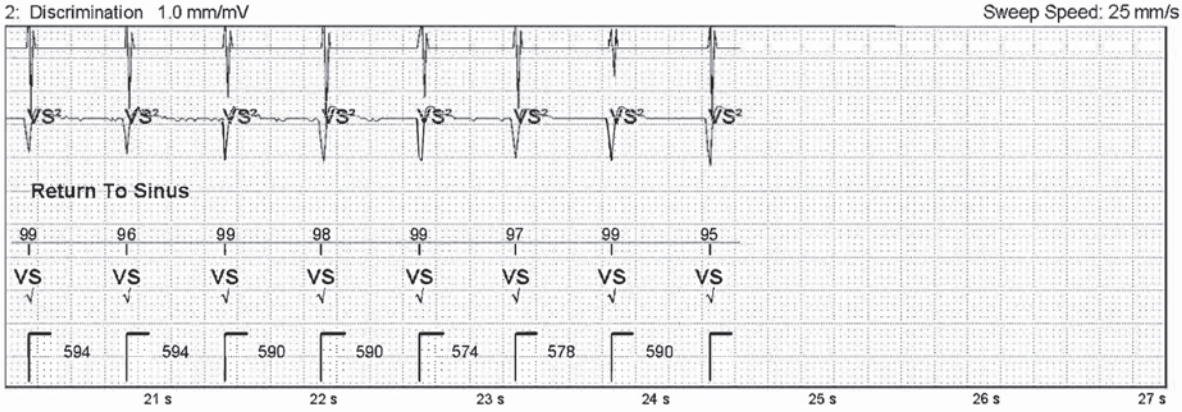


ST. JUDE MEDICAL

3 Jun 2016
11:25
Archive

Episode: VT (190 bpm / 315 ms)

19 Apr 2015 21:27

Duration	00:22 (M:S)	**Alerts**	**Therapy accelerated rhythm**
Detection Criteria	162 - 213 bpm	⚠	**ATP therapy unsuccessful**

Therapy	**Results**
1) ATP	1) Accel to VF
2) Defib 30.0 J (798V)	2) Below Rate Detection (CL 660 ms)

HV Therapy	
Last HV Lead Impedance	90 Ω
Last Charge Time	7.5 sec
Delivered PW	+8.9 ms, -8.9 ms

ATP Therapy Details
VT ATP Therapy

Therapy 1
* Burst 1 252, 242, 232, 222, 212, 202, 200 ms

*Min BCL reached in burst

Diagnosis Summary

	Diagnosis
	VT
Time to Diagnosis	4.75 sec
Rate (CL)	190 bpm (315 ms)
Zone	VT
VT Diagnosis Criteria	2 of 3

Morphology	On, ≥ 90% is a match, ≥ 3 matches indicate SVT	
Min Match Score	n/a	
Max Non-Match Score	62%	
No. Template Matches	0 of 10	**(VT Indicated)**
Sudden Onset	On, < 20 % indicates SVT	
Max Delta	69 %	**(VT Indicated)**
Interval Stability	On w/SIH, ≥ 40 ms or SIH Count ≥ 2 intervals indicates SVT	
Stability Delta	10 ms	
SIH Count	0	**(VT Indicated)**

SVT Criteria Statistics
SVT Diagnoses during this episode 0

Measured SVT Discriminator values through initial VT/VF Diagnosis

Min Match Score	n/a	Min/Max Stability Delta	10 ms /10 ms
Max Non-Match Score	62 %	Min/Max SIH Count	0 / 0
Template Used	19 Apr 2015 20:23	Max Onset Delta	69 %

DeFT Response™ Settings (Shock Waveform)			**1st Phase**	**2nd Phase**
Waveform	Biphasic	VF Shocks (Defib)	65 %	65 %
Waveform Mode	Tilt	VT Shocks (CVRT)	Same as Defib	Same as Defib
Shock Configuration	RV to Can			
RV Polarity	Anode(+)			
Defib Max Sensitivity	0.5 mV			

ST. JUDE MEDICAL

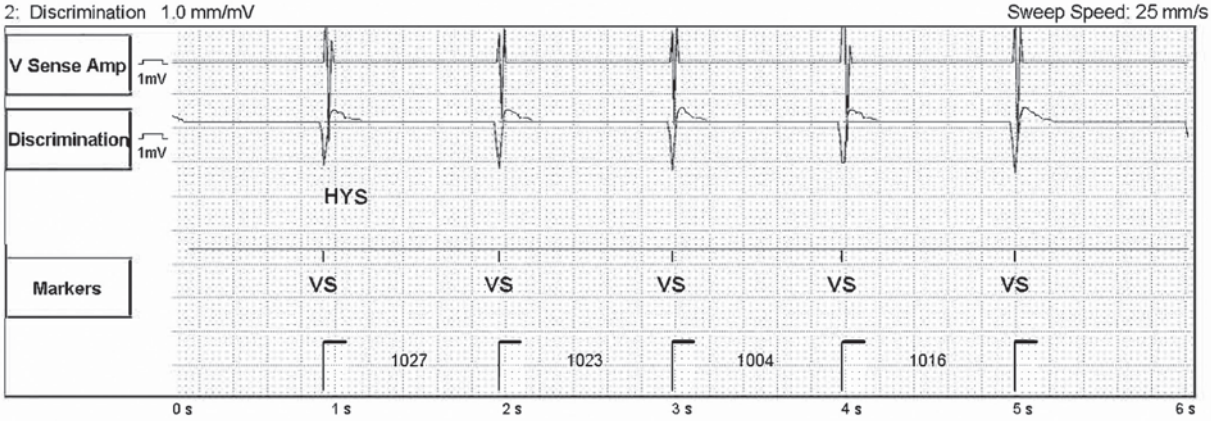
3 Jun 2016
11:25
Archive

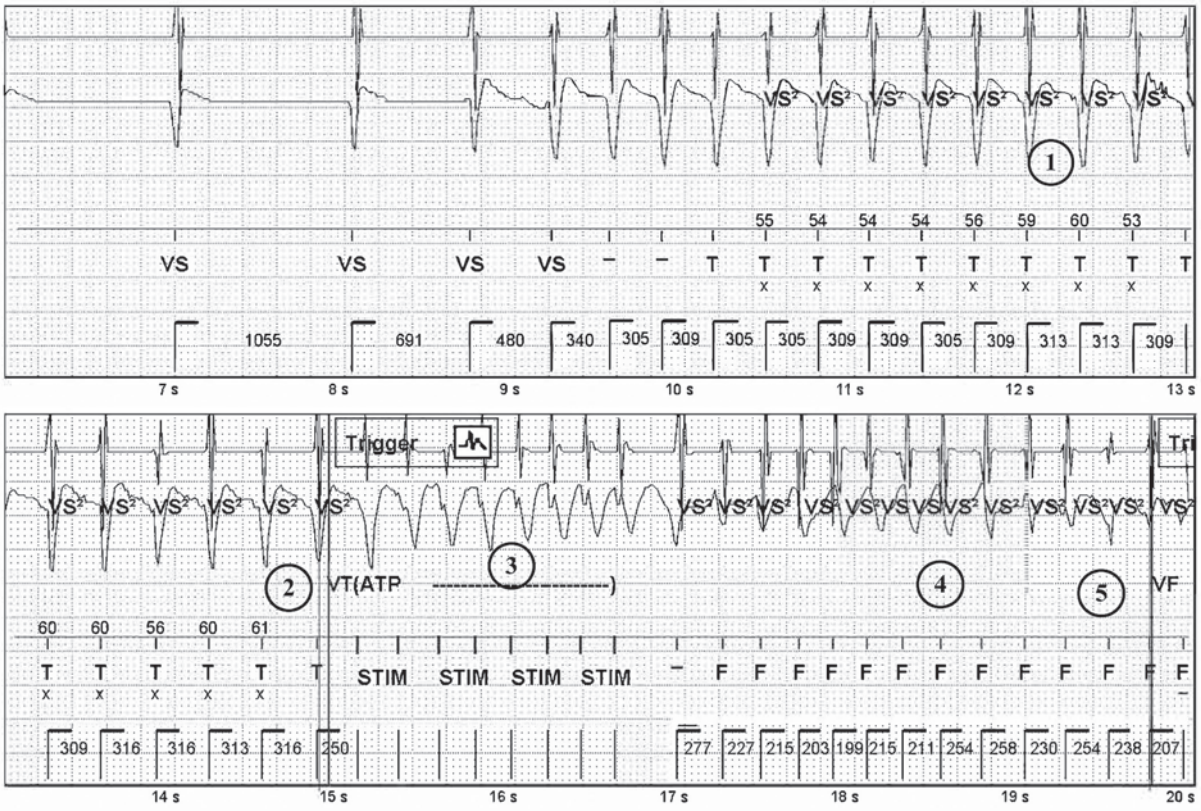
Episode: VT (190 bpm / 315 ms)

19 Apr 2015 21:27

1: V Sense Amp 1.0 mm/mV
2: Discrimination 1.0 mm/mV
3: Markers

Sweep Speed: 25 mm/s





ST. JUDE MEDICAL

3 Jun 2016
11:25
Archive

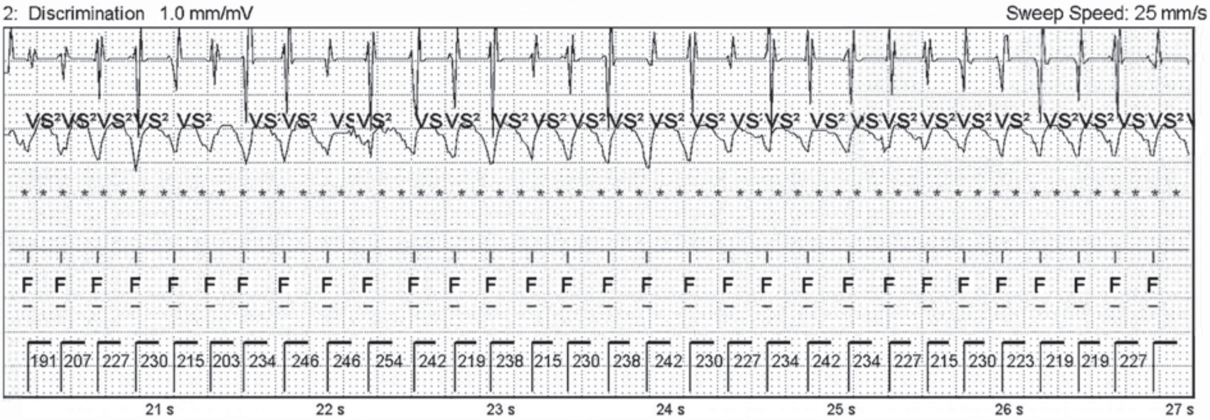
Episode: VT (190 bpm / 315 ms) (Continued)

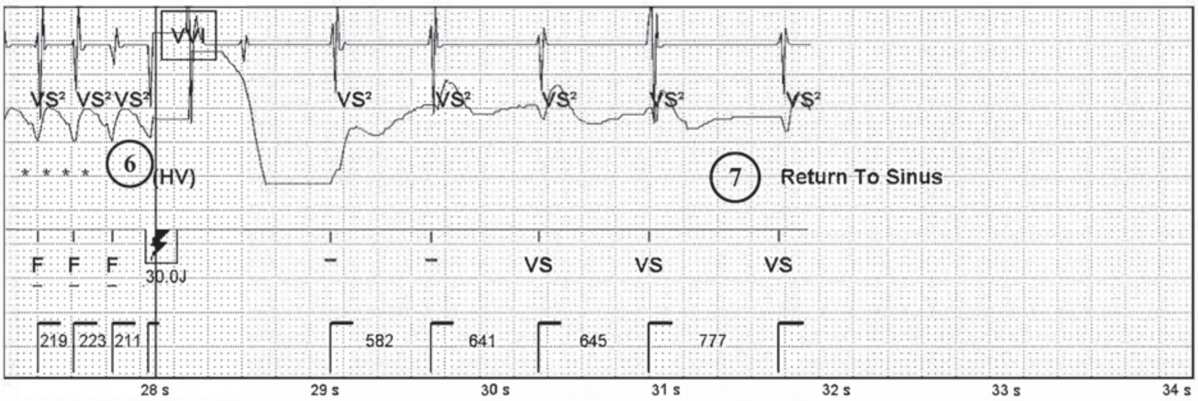
19 Apr 2015 21:27

VT/VF Episode 8 of 10
Page 3 of 3

1: V Sense Amp 1.0 mm/mV   3: Markers
2: Discrimination 1.0 mm/mV

Sweep Speed: 25 mm/s





Tracing 2: antitachycardia pacing in the VF zone

Patient

This 57-year-old man received a Saint Jude Medical Ellipse™ VR ICD for the management of hypertrophic cardiomyopathy complicated by episodes of symptomatic sustained VT. Multiple episodes of VT recorded in the device memory were observed during a routine visit.

Tracing 2A

1: probable sinus tachycardia; cycles classified VS;
2: sudden acceleration of the tachycardia with cycles classified in the VF zone; fast and regular tachycardia, with change in morphology of the ventricular EGM (criterion in favor of a ventricular origin): probable fast VT detected in the VF zone;
3: the VF counter is full (12);
4: ATP during the charge; onset of charge during a sequence of ATP (burst of 8 complexes);
5: relatively short charge (a previous, incomplete charge without shock delivery is visible in the beginning of the tracing) though the shock could not be delivered in absence of a fast cycle; the burst was successful and restored sinus rhythm; after 3 consecutive VS-classified cycles, return to sinus rhythm was diagnosed;

Tracing 2B

1: probable sinus tachycardia;
2: probable fast VT detected in the VF zone;
3: the VF counter is full (12);
4: ATP during the charge; onset of charge during a sequence of ATP (burst of 8 complexes);
5: the burst was successful and restored sinus rhythm; after 3 consecutive cycles classified VS, return to sinus rhythm was diagnosed and the charge was aborted;

Tracing 2C

The patient was seen again and the device was reprogrammed (ATP preceding the charge in the VF zone)

1: probable sinus tachycardia;
2: probable fast VT detected in the VF zone;
3: the VF counter is full (20);
4: ATP preceding the charge; sequence of ATP (burst of 8 complexes) without charge of the capacitors;
5: unsuccessful burst; the arrhythmia continues;
6: after 6 F classified cycles, VF is redetected and the capacitors begin to charge;
7: persistence of tachyarrhythmia; at the end of the charge, a 30-J shock is delivered on the second (short) cycle following the end of charge;
8: successful shock;

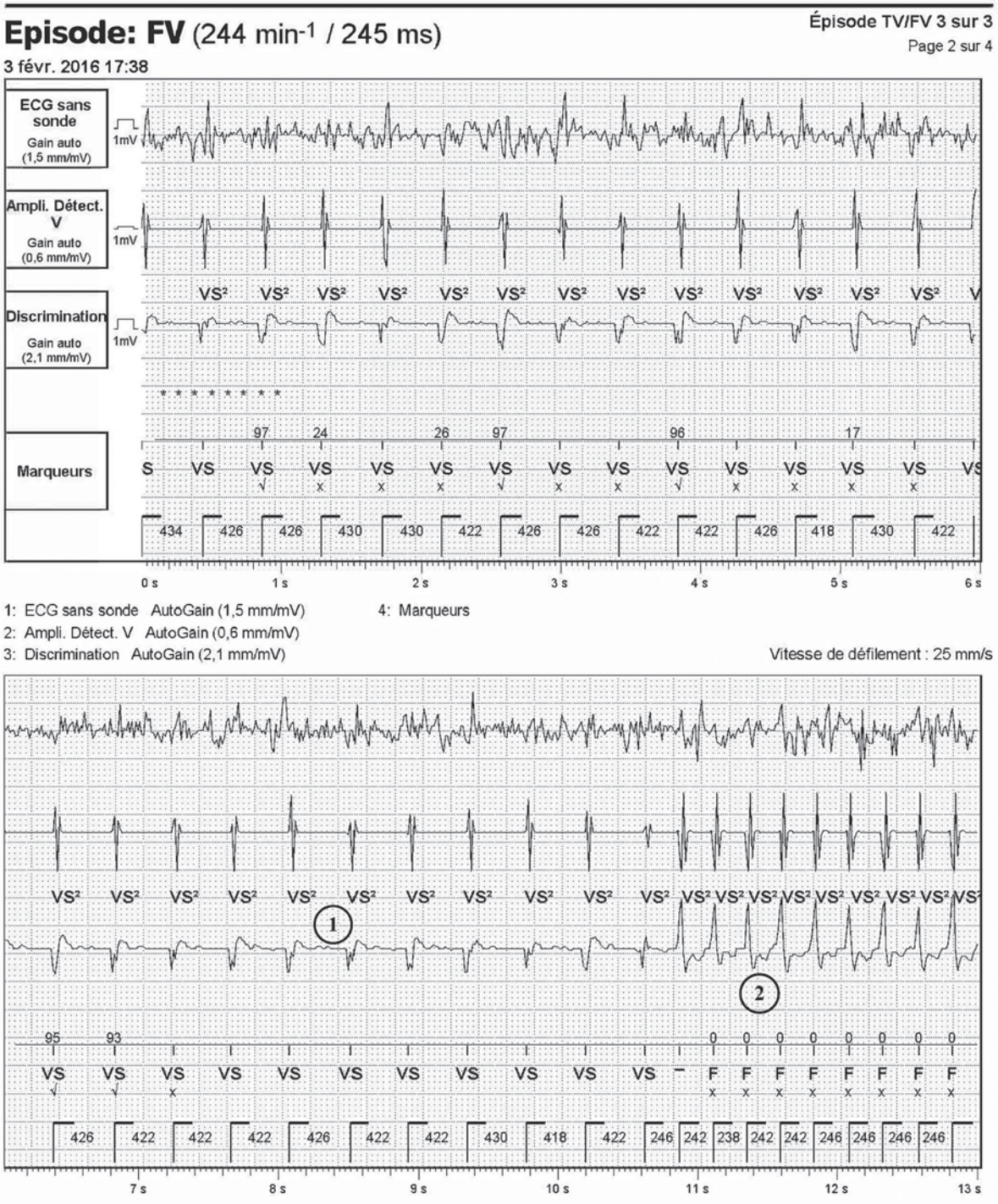
Comments

One of the main objectives when programming an ICD is to minimize to a maximum the number of shocks while preserving the patient's safety. A considerable proportion of fast tachycardias diagnosed in the VF zone is organized and monomorphous and can be terminated by ATP. However, in the past, doubts regarding the efficacy of ATP and fear of accelerating the arrhythmia and threatening the patient's prognosis have limited its use for the treatment of very fast tachycardias. While the efficacy of electric shocks in the termination of fast ventricular arrhythmias is unquestionable, they are painful and increase considerably the energy consumption. The delivery of several consecutive shocks is a cause of premature depletion of the batteries and of noticeable lowering of the quality of life. Several cases have been reported of depression or anxiety caused by the delivery of a series

of shocks. Furthermore, the adverse effects of electric shocks have been clearly shown, including a significant shortening of survival with the number of shocks delivered. Several studies have found that the use of ATP sequences in the VF zone a) is effective and painless, b) limits the consumption of the batteries, and c) considerably improves quality of life, thus should be used as a first therapy, including in the VF zone. It is a class I indication in the updated professional guidelines. In this patient, the considerably fewer shocks delivered compared with the programming of shocks exclusively in the VF zone represents a clear advantage. The newer defibrillators made by St. Jude Medical enable the programming of ATP during or before the charge.

When ATP is programmed during the charge, the diagnosis of VF triggers simultaneously the charge of the capacitors and the sequence of ATP. The characteristics of ATP during the charge are the same as those of the first ATP sequence of the fastest VT zone. The shock is not delivered if the sequence is successful. The clear advantage is the termination of the tachycardia without shock delivery, a key factor in the preservation of quality of life and prognosis of the patient. On the other hand, the charge of the capacitor consumes energy, which may be problematic if the episodes are repetitive. A charge to the highest level consumes, depending on the manufacturer, energy corresponding to 10 to 20 days of normal battery consumption.

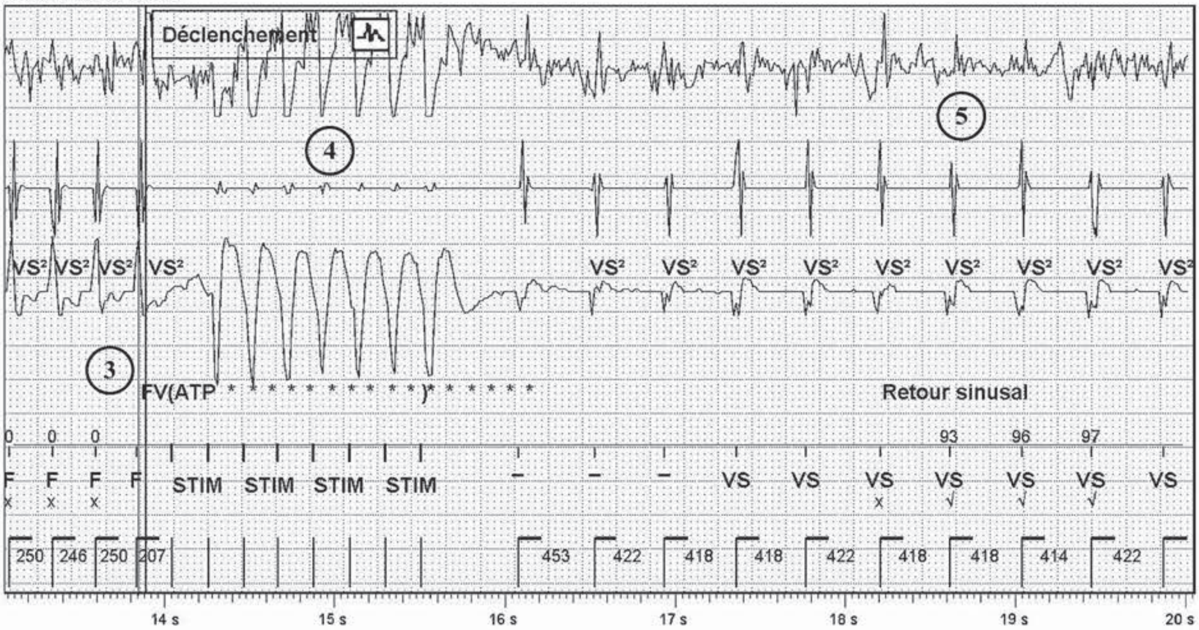
ATP preceding the charge may lower the consumption of energy. Once the diagnosis of VF made, ATP is delivered. When VF is reconfirmed after the delivery of ATP, the charge of the capacitor begins. If the arrhythmia is terminated, the charge is not initiated. Thus, successful ATP spares the charge of the capacitors. Conversely, unsuccessful ATP delays the shock delivery by a few seconds.


Episode: FV (244 min-1 / 245 ms)
Épisode TV/FV 3 sur 3
Page 2 sur 4
3 févr. 2016 17:38
ECG sans sonde
Gain auto (1,5 mm/mV)
1mV
Ampli. Détect. V
Gain auto (0,6 mm/mV)
Discrimination
Gain auto (2,1 mm/mV)
Marqueurs
0 s
1 s
2 s
3 s
4 s
5 s
6 s
1: ECG sans sonde AutoGain (1,5 mm/mV)
2: Ampli. Détect. V AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (2,1 mm/mV)
4: Marqueurs
Vitesse de défilement : 25 mm/s
7 s
8 s
9 s
10 s
11 s
12 s
13 s
Épisode TV/FV 3 sur 3 Page 2 sur 4
4 févr. 2016 4:00 (CET)

Episode: FV (244 min^{-1} / 245 ms) (Continued)

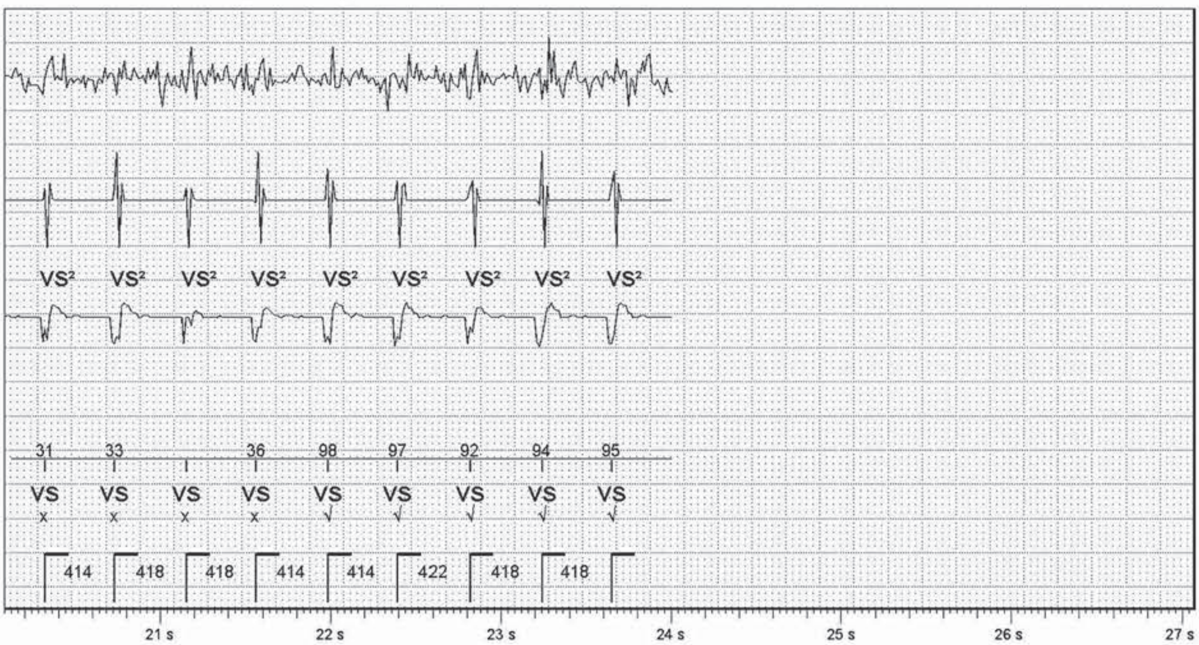
Épisode TV/FV 3 sur 3
Page 3 sur 4

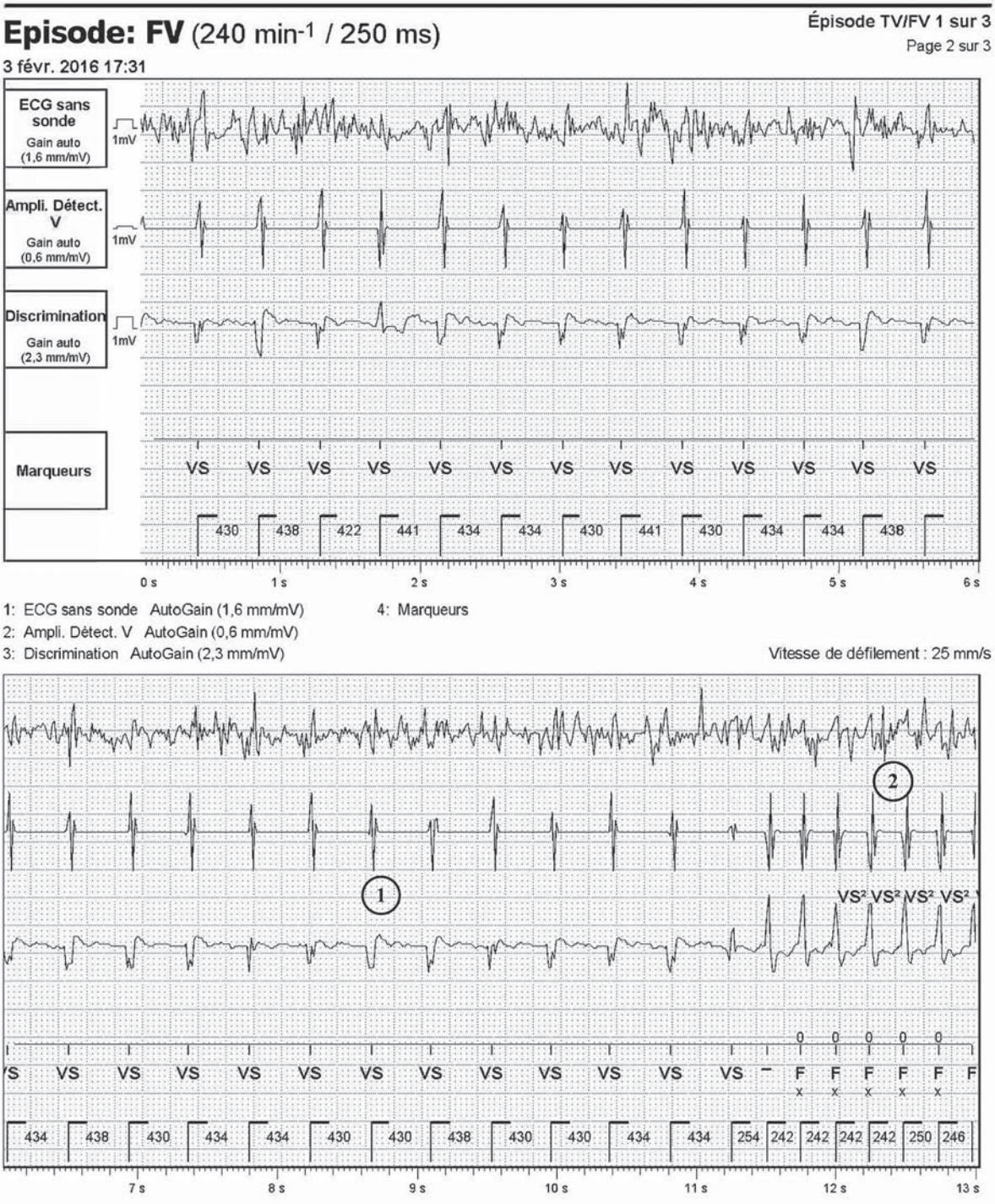
3 févr. 2016 17:38



1: ECG sans sonde AutoGain (1,5 mm/mV)
2: Ampli. Détect. V AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (2,1 mm/mV)
4: Marqueurs

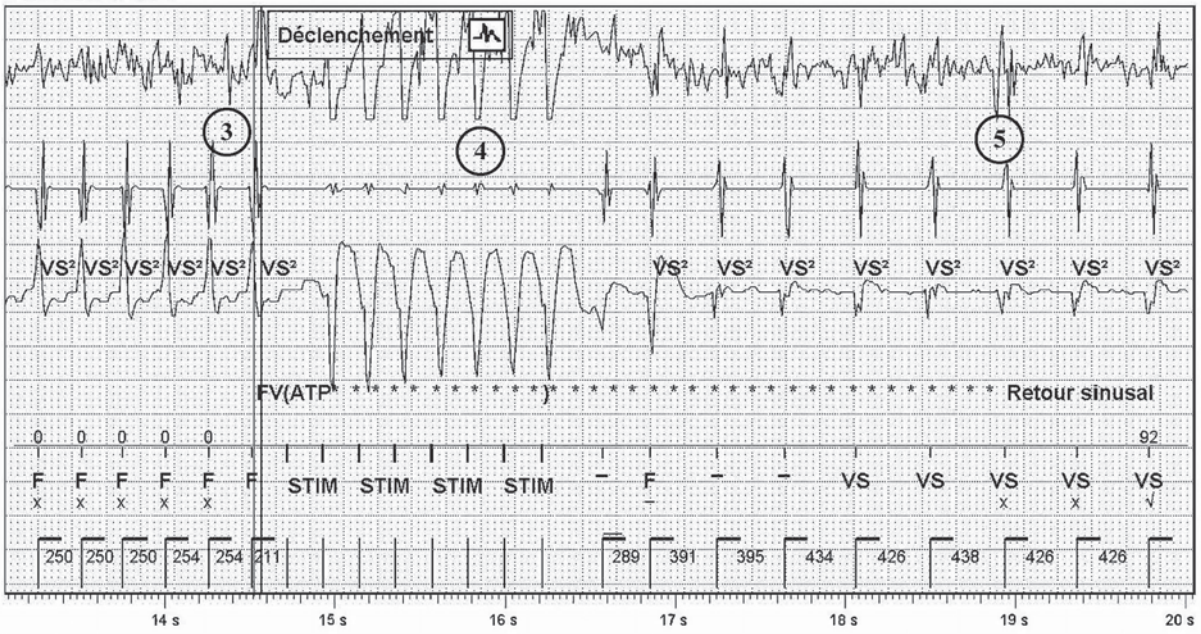
Vitesse de défilement : 25 mm/s




Episode: FV (240 min-1 / 250 ms)
Épisode TV/FV 1 sur 3
Page 2 sur 3
3 févr. 2016 17:31
ECG sans sonde
Gain auto (1,6 mm/mV)
1mV
Ampli. Détect. V
Gain auto (0,6 mm/mV)
1mV
Discrimination
Gain auto (2,3 mm/mV)
1mV
Marqueurs
VS VS VS VS VS VS VS VS VS VS VS VS VS
430 438 422 441 434 434 430 441 430 434 434 438
0 s 1 s 2 s 3 s 4 s 5 s 6 s
1: ECG sans sonde AutoGain (1,6 mm/mV)
2: Ampli. Détect. V AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (2,3 mm/mV)
4: Marqueurs
Vitesse de défilement : 25 mm/s
1
2
VS² VS² VS² VS²
VS VS VS VS VS VS VS VS VS VS VS VS VS F F F F F F
434 438 430 434 434 430 430 438 430 430 434 434 254 242 242 242 242 250 246
7 s 8 s 9 s 10 s 11 s 12 s 13 s
Épisode TV/FV 1 sur 3 Page 2 sur 3
4 févr. 2016 4:00 (CET)

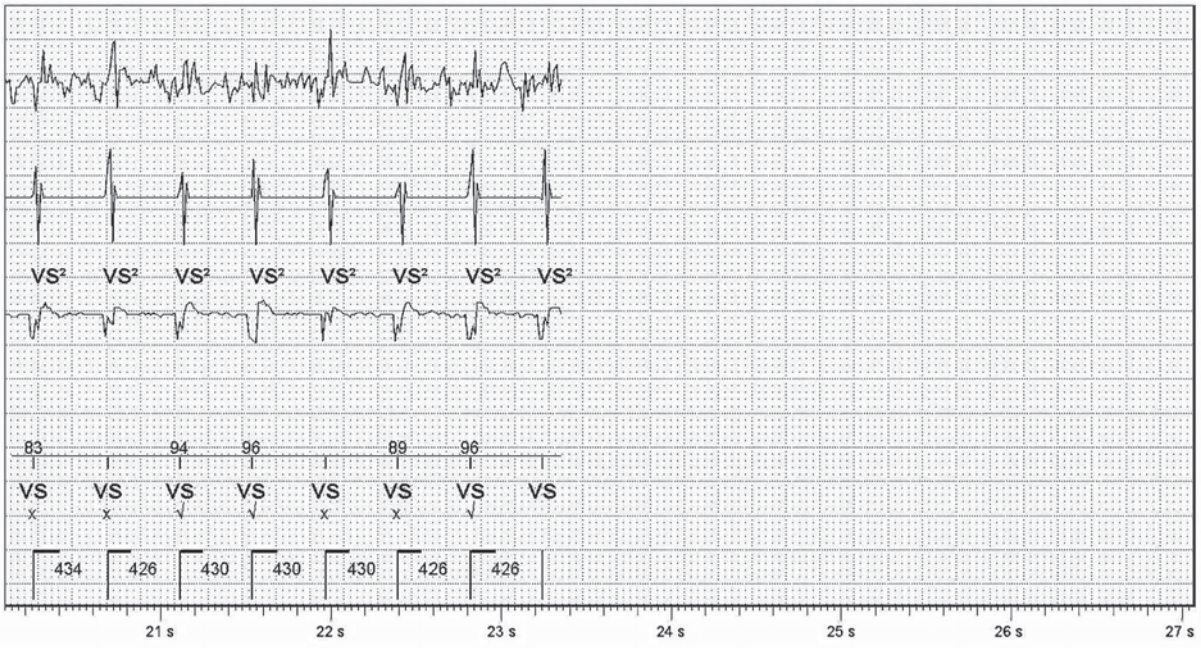
Episode: FV (240 min^{-1} / 250 ms) (Continued)

3 févr. 2016 17:31



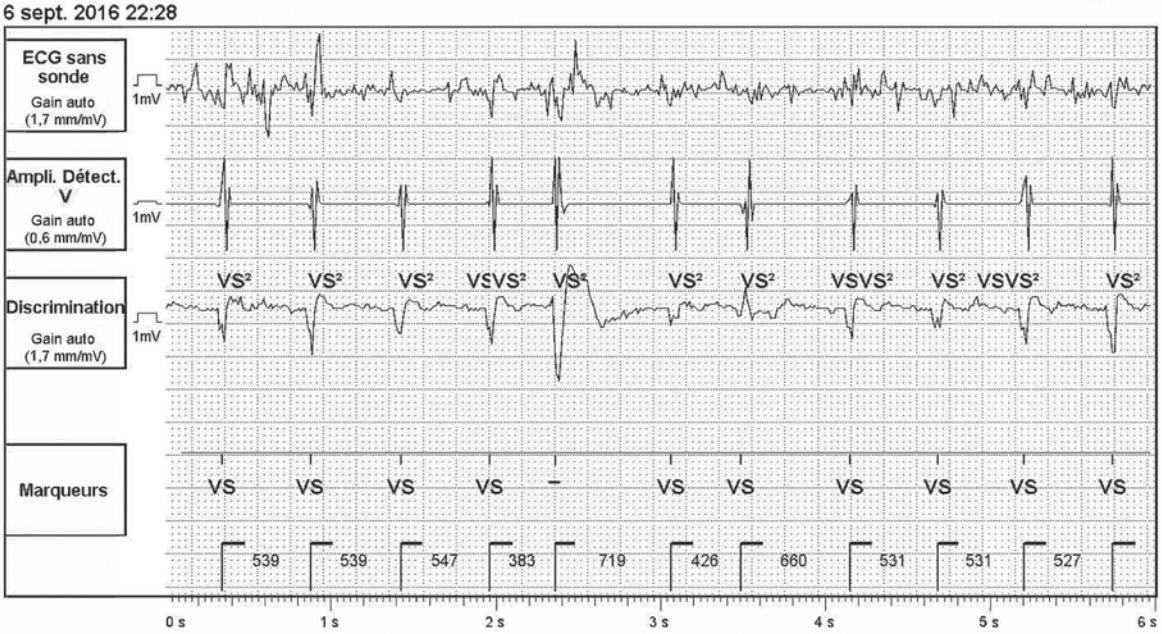
1: ECG sans sonde AutoGain (1,6 mm/mV)
2: Ampli. Détect. V AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (2,3 mm/mV)
4: Marqueurs

Vitesse de défilement : 25 mm/s



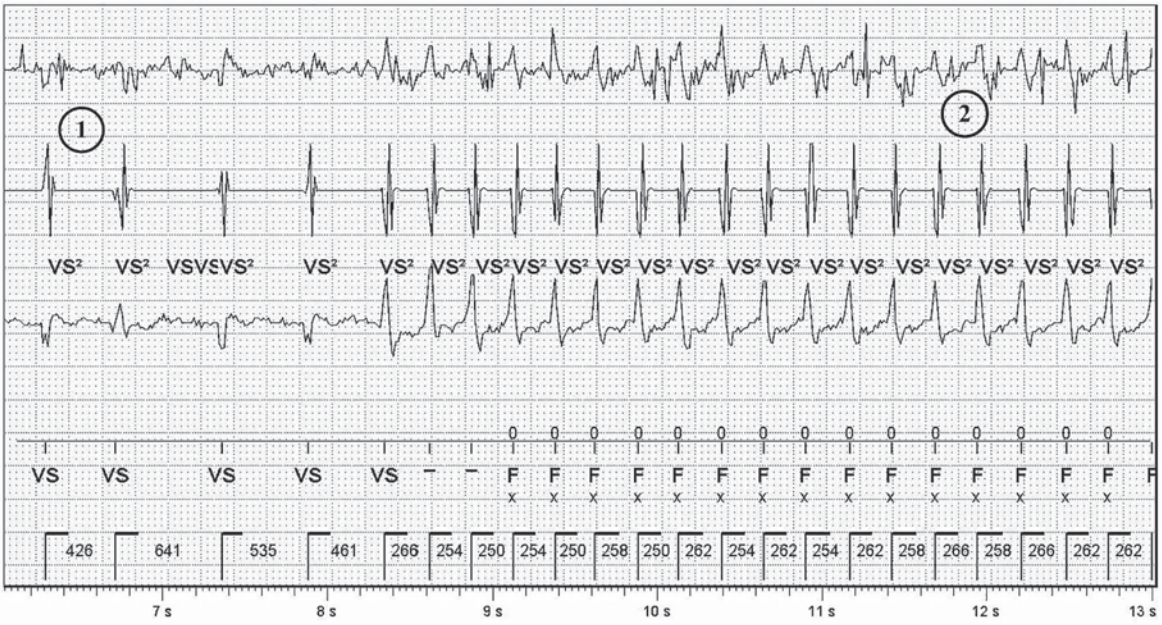
Episode: FV (230 min^{-1} / 260 ms)

6 sept. 2016 22:28



1: ECG sans sonde AutoGain (1,7 mm/mV)
2: Ampli. Détect. V AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (1,7 mm/mV)
4: Marqueurs

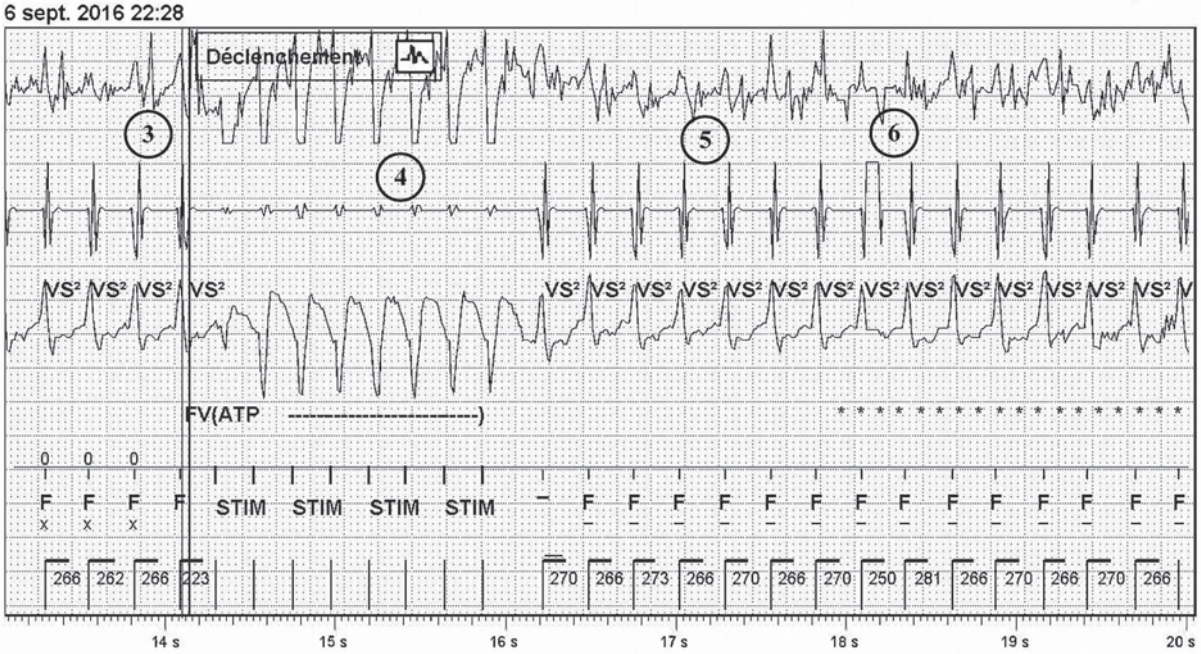
Vitesse de défilement : 25 mm/s



Episode: FV (230 min^{-1} / 260 ms) (Continued)

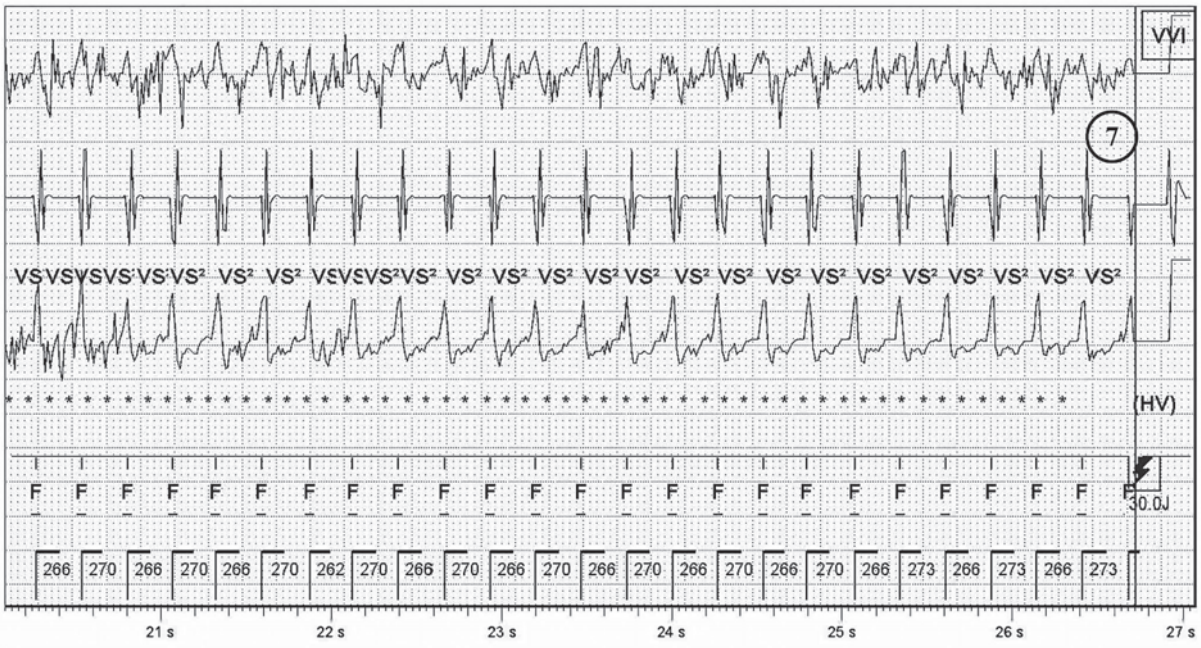
Épisode TV/FV 1 sur 1
Page 3 sur 5

6 sept. 2016 22:28



1: ECG sans sonde AutoGain (1,7 mm/mV)
2: Ampli. Détect. V AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (1,7 mm/mV)
4: Marqueurs

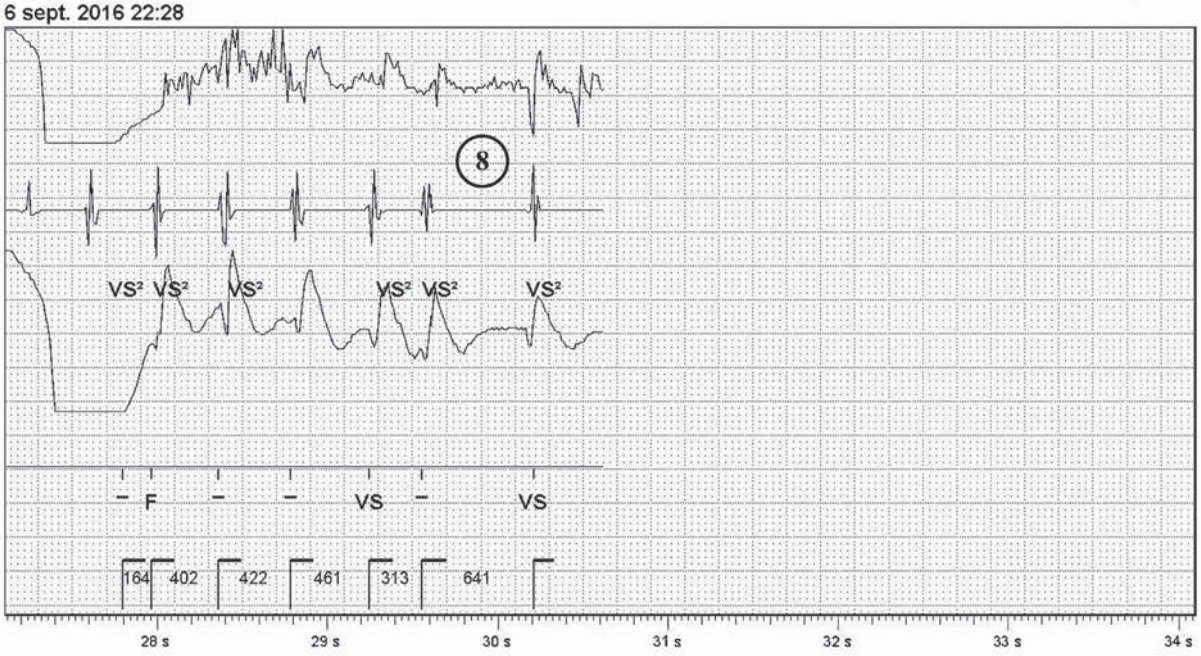
Vitesse de défilement : 25 mm/s



Episode: FV (230 min^{-1} / 260 ms) (Continued)

Épisode TV/FV 1 sur 1
Page 4 sur 5

6 sept. 2016 22:28



1: ECG sans sonde AutoGain (1,7 mm/mV)
2: Ampli. Détect. V AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (1,7 mm/mV)
4: Marqueurs

Vitesse de défilement : 25 mm/s

Tracing 3: single chamber discrimination

Patient

This 37-year-old man received a Saint Jude Medical Ellipse™ VR defibrillator for the management of hypertrophic cardiomyopathy complicated by episodes of sustained VT and episodes of AF with a rapid ventricular response. He was seen in consultation after receiving a shock in absence of loss of consciousness. Multiple episodes were recorded in the device memory.

Tracing 3A

1: irregular tachycardia with alternans between cycles classified VS, - , T1 and T2;
2: the VT2 counter is filled; diagnosis of SVT (the 3 discrimination criteria are in favor of SVT: gradual onset, irregular ventricular rhythm, morphology similar to the reference QRS); inhibition of the therapies;
3: VT2 counter filled in redetection (6 T2 classified cycles); diagnosis of SVT;
4: interruption of EGM recording;
5: new diagnosis of SVT;
6: return to sinus rhythm was diagnosed and end of episode after 3 consecutive cycles classified VS;

Tracing 3B

1: irregular tachycardia with alternans between cycles classified VS, - , T1 and T2;
2: the VT1 counter is filled; diagnosis of SVT (discordance between parameters since sudden onset is present); inhibition of the therapies;
3: return to sinus rhythm diagnosed and end of episode after 3 consecutive VS classified cycles;

Tracing 3C

1: irregular tachycardia with alternans between cycles classified VS, - , T1 and T2;
2: the VT2 counter is filled; diagnosis of SVT (the 3 criteria of discrimination are in favor of SVT: sudden onset, irregular ventricular rhythm, morphology similar to reference QRS); inhibition of the therapies;
3: VT2 counter filled in redetection (6 T2 classified cycles); diagnosis of SVT;
4: subtle acceleration of the tachycardia without change in morphology of the ventricular EGM; VF counter filled in redetection (6 F classified cycles); absence of discrimination; diagnosis of VF;
5: ATP during the charge;
6: at the end of the charge, absence of return to sinus rhythm; 30 J shock delivered on a short cycle (classified F);
7: slowing of the rate and return to sinus rhythm;

Comments

The morphology analysis has been completely modified in the recent devices manufactured by St. Jude Medical. In the older ICD, the morphology was based on an analysis of the bipolar detection channel (near-field), presenting several limitations, as the bipolar signal reflected only the local depolarization near the electrode. On the newer ICD, the bipolar channel is only used to synchronize with the reference pattern, since the morphology is analyzed on the discrimination channel (between the RV coil and the can or between the distal electrode and the can) enabling a finer discrimination. The far-field signal encompasses the overall depolarization of both ventricles and resembles the surface ECG. Based on comparisons with the reference pattern, a correlation score (percentage of similarity) is calculated for each QRS of the tachyarrhythmia, using eight regularly spaced points on the QRS complex (far-field channel). The update of the morphology is also more frequent and more progressive than on the older patterns.
These changes have significantly improved the performance of the algorithm. The latest guidelines recommend basing the single chamber discrimination on this morphology criterion only. These

tracings illustrate the limits of the sudden onset criterion in the diagnosis of an episode of AF. The nominal programming (2/3) with the 3 criteria activated is the cause of several inappropriate therapies when AF becomes regular for a few cycles (sudden onset and regular rhythm in favor of VT). When the morphology criterion functions flawlessly, as in this patient, it may be advisable to limit the discrimination on this criterion only.

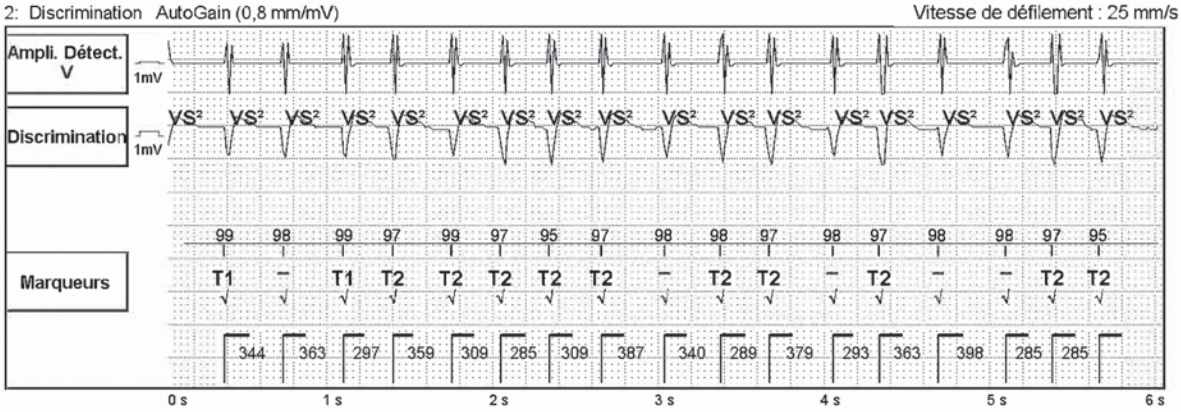
A second key point illustrated by these tracings is the rate limits within which discrimination must function. In ICD made by St. Jude Medical, since discrimination is not operative in the VF zone, the programming of the lower limit of that zone is critical. In this patient, the morphology analysis enabled an accurate diagnosis of SVT, regardless of the ventricular rate. A subtle rate acceleration and classification of the intervals in the VF zone triggered an inappropriate electric shock while the patient was conscious, which had a pronounced negative effect on his mood. To solve this problem, the professional practice guidelines recommend the programming of a VF zone from 250 bpm, with the ability to discriminate the origin of the arrhythmia up to a rate of ≥230 bpm.

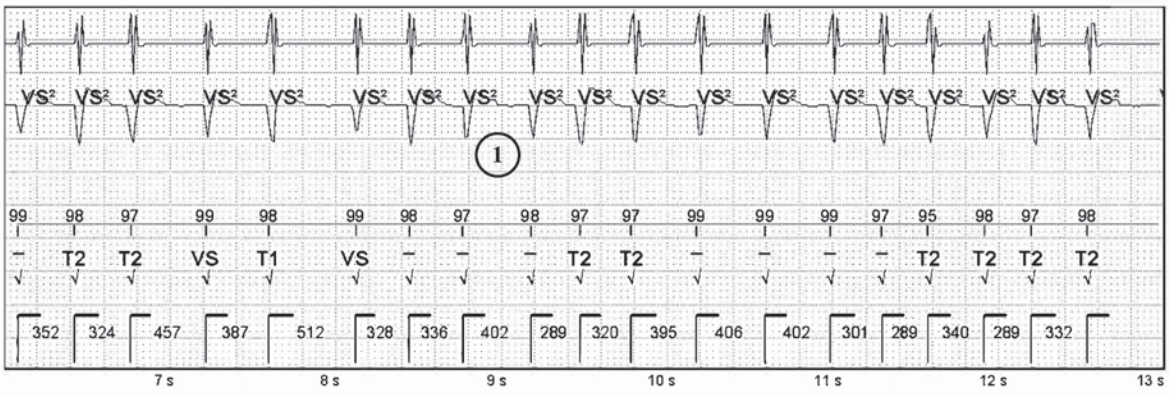
Episode: TSV (171 min^{-1} / 350 ms)

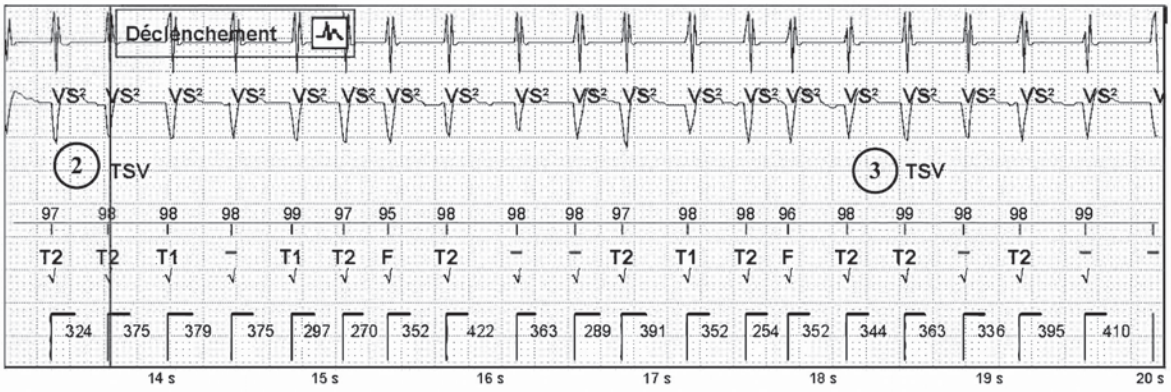
8 févr. 2016 7:08

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,8 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s





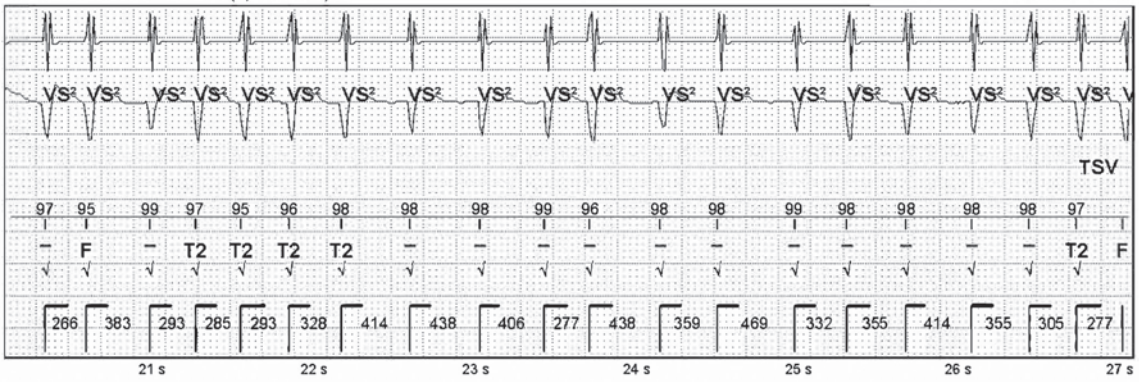


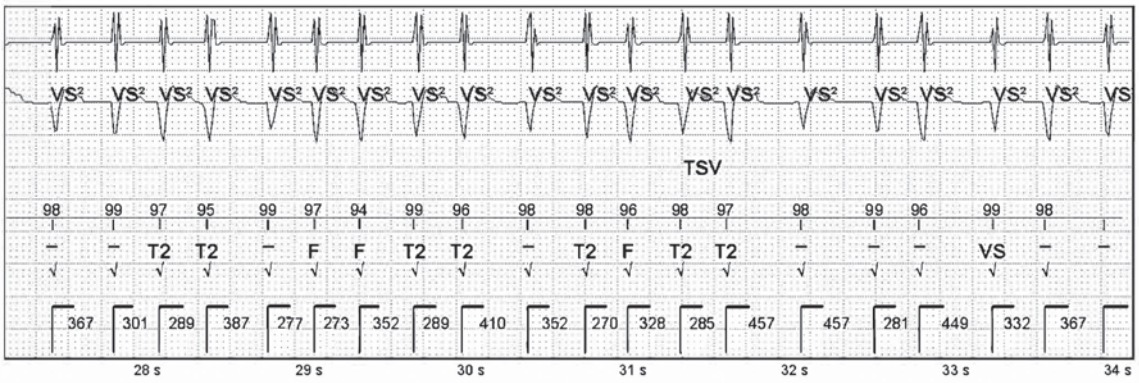
Episode: TSV (171 min^{-1} / 350 ms) (Continued)

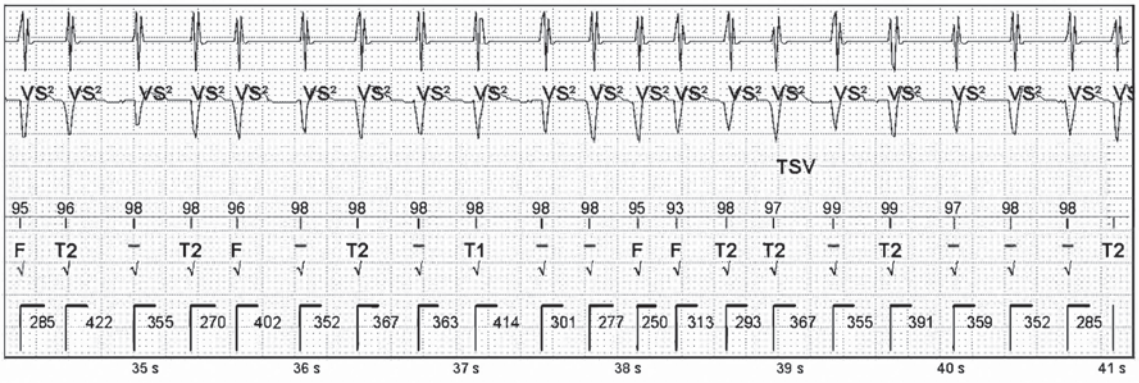
8 févr. 2016 7:08

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,8 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s





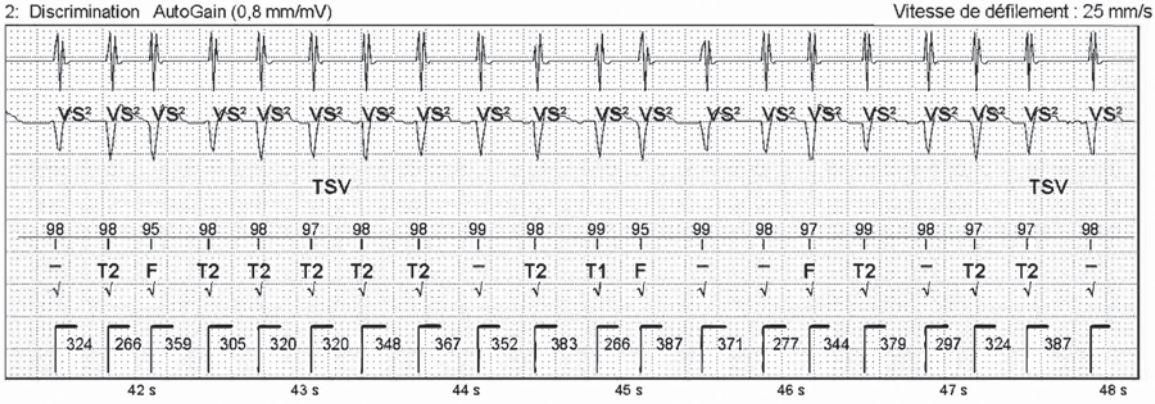


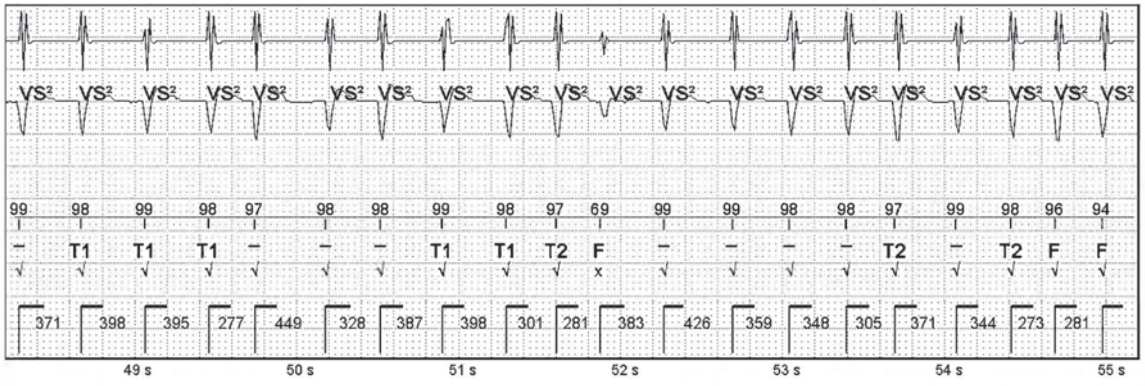
Episode: TSV (171 min^{-1} / 350 ms) (Continued)

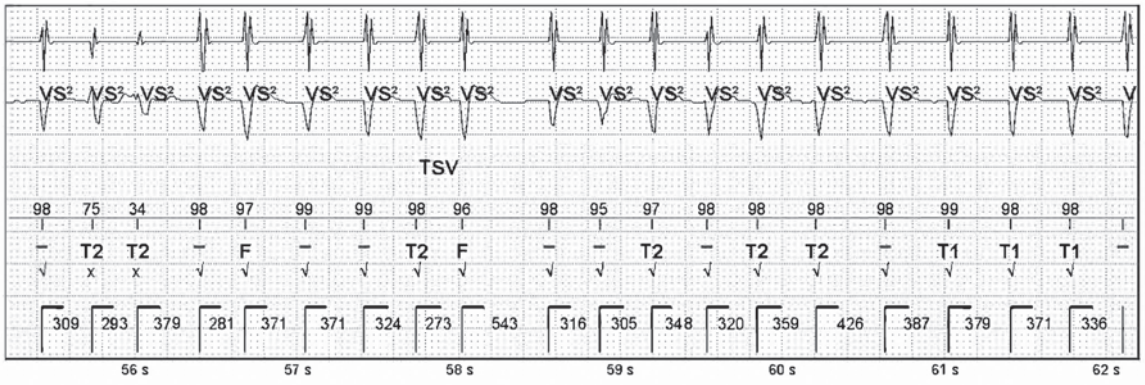
8 févr. 2016 7:08

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,8 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s





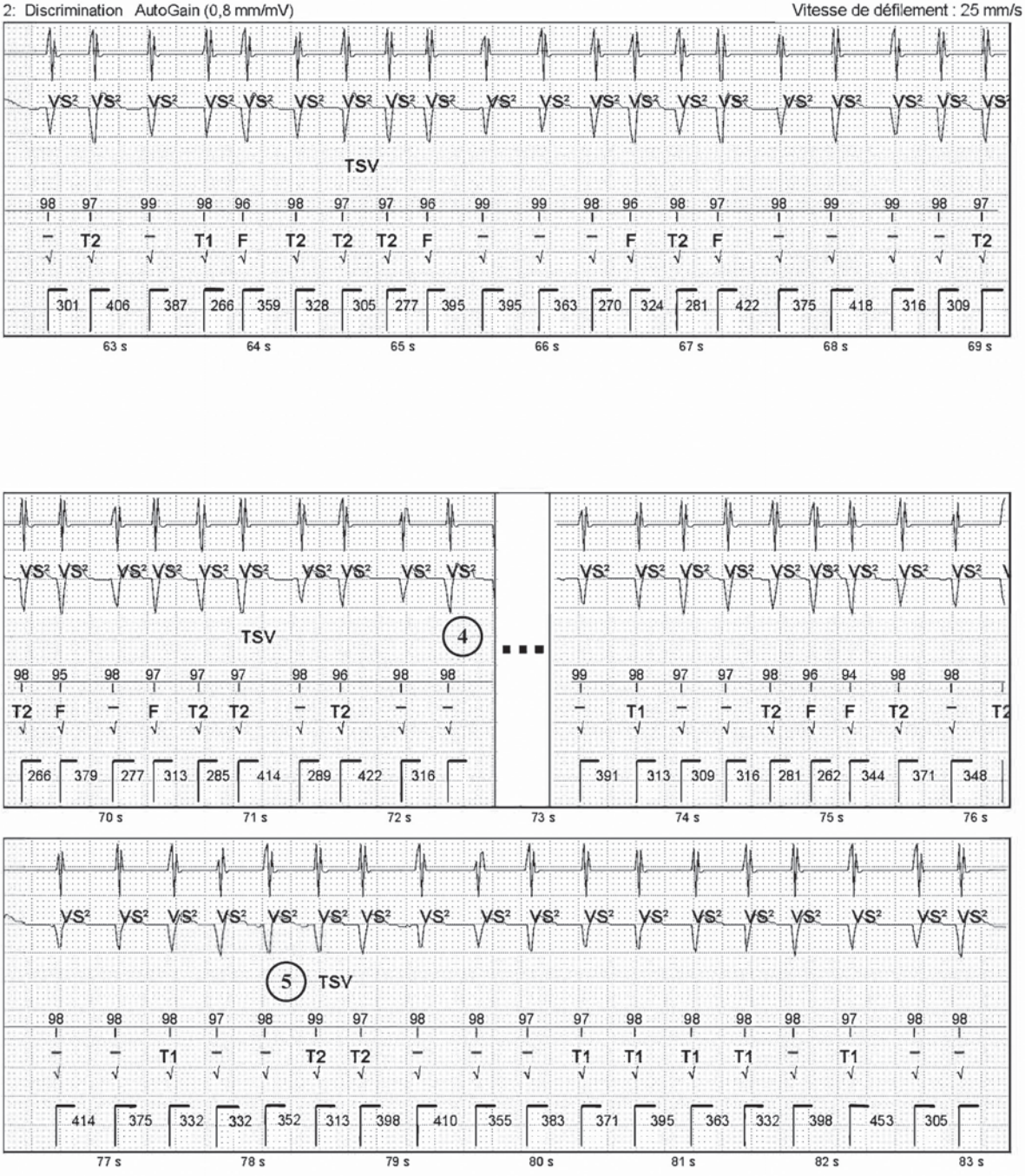


Episode: TSV (171 min^{-1} / 350 ms) (Continued)

8 févr. 2016 7:08

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,8 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s

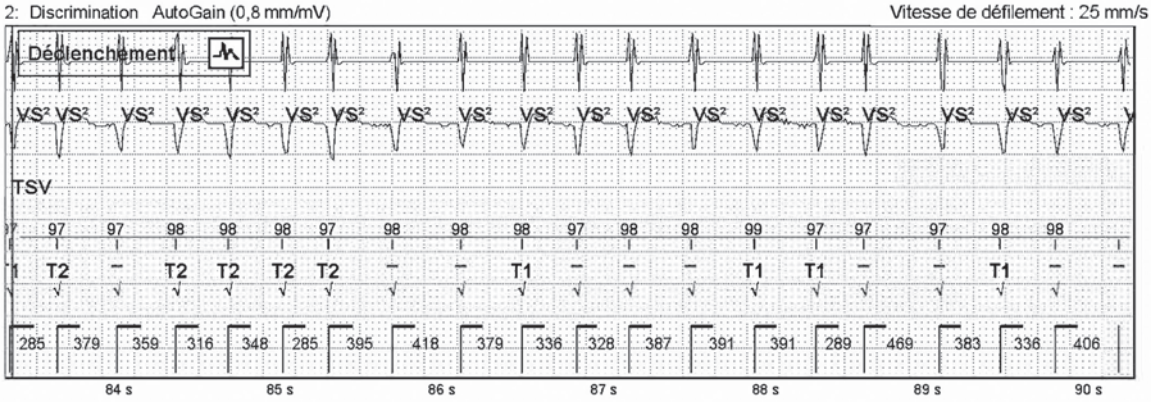


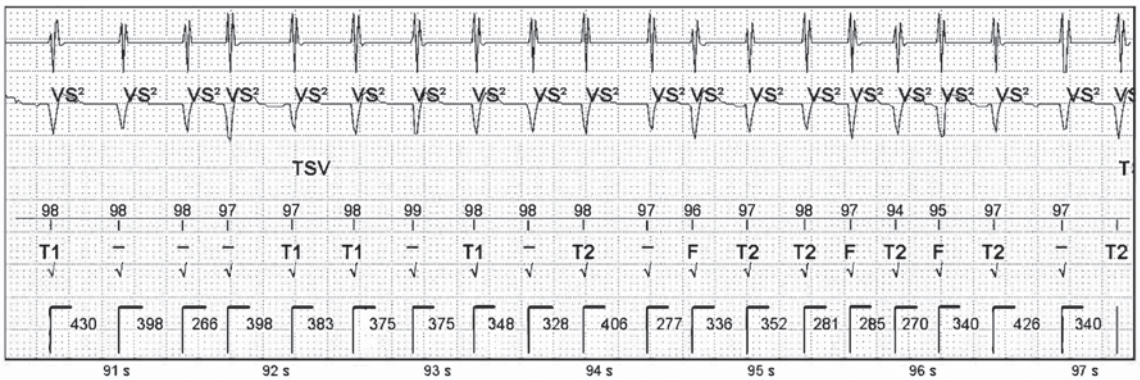
Episode: TSV (171 min^{-1} / 350 ms) (Continued)

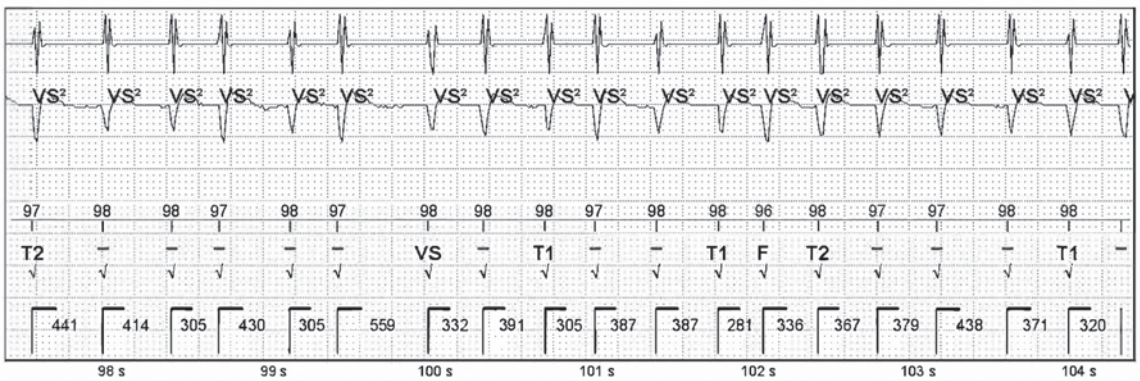
8 févr. 2016 7:08

1: Ampli. Détect. V AutoGain (0,4 mm/mV) 3: Marqueurs
2: Discrimination AutoGain (0,8 mm/mV)

Vitesse de défilement : 25 mm/s





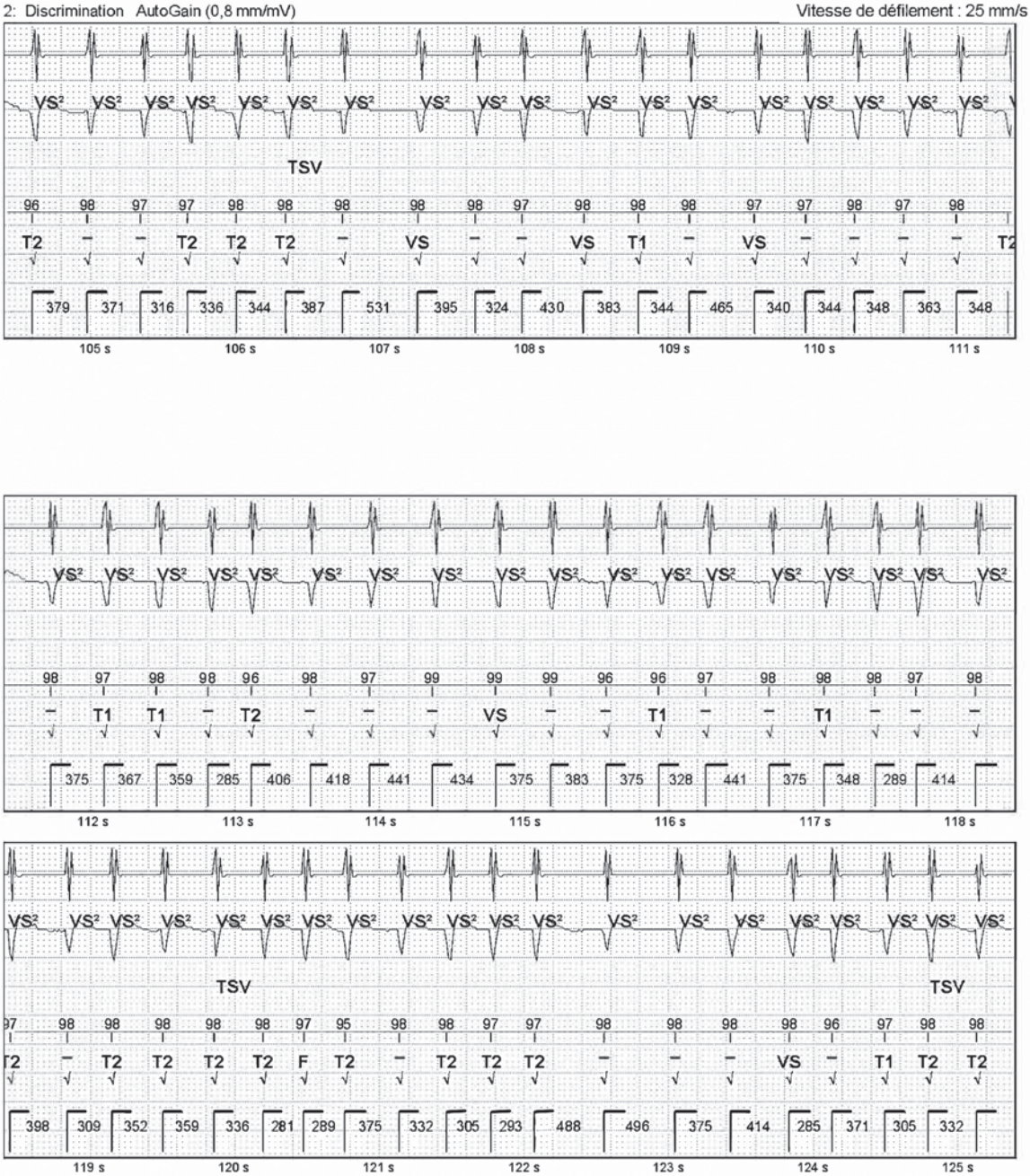


Episode: TSV (171 min^{-1} / 350 ms) (Continued)

8 févr. 2016 7:08

1: Ampli. Détect. V AutoGain (0,4 mm/mV) 3: Marqueurs
2: Discrimination AutoGain (0,8 mm/mV)

Vitesse de défilement : 25 mm/s

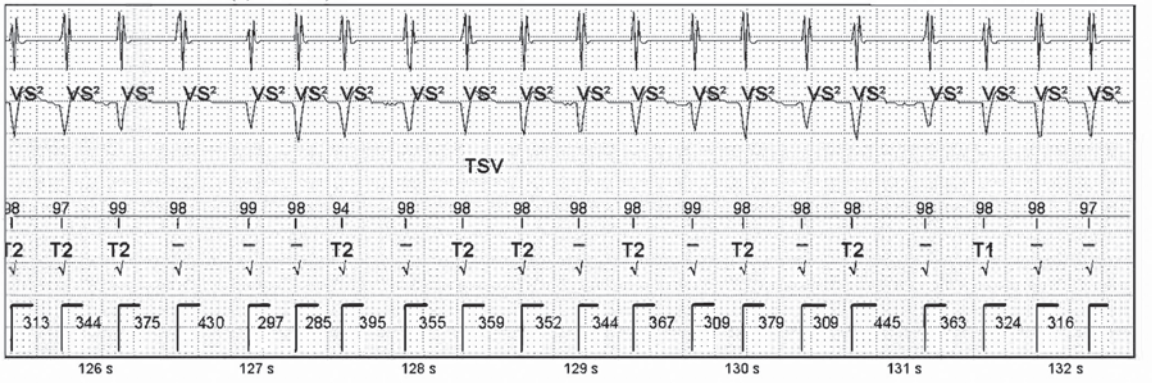


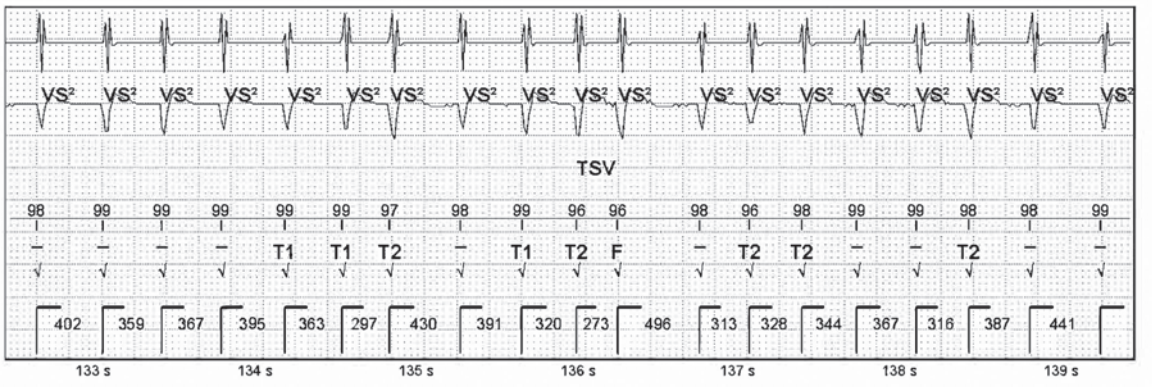
Episode: TSV (171 min^{-1} / 350 ms) (Continued)

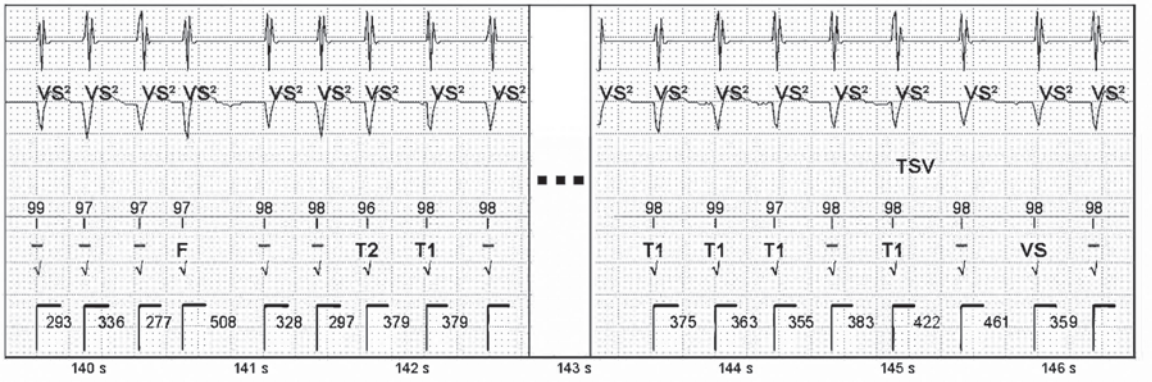
8 févr. 2016 7:08

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,8 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s







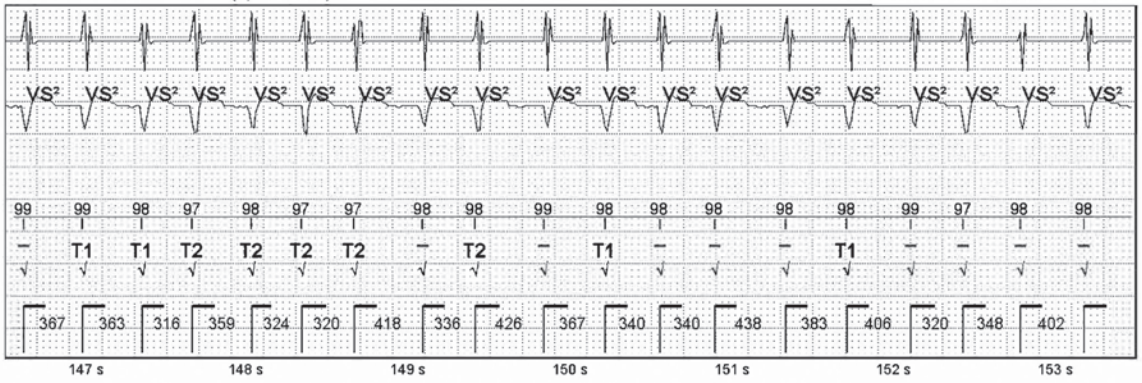
Episode: TSV (171 min^{-1} / 350 ms) (Continued)

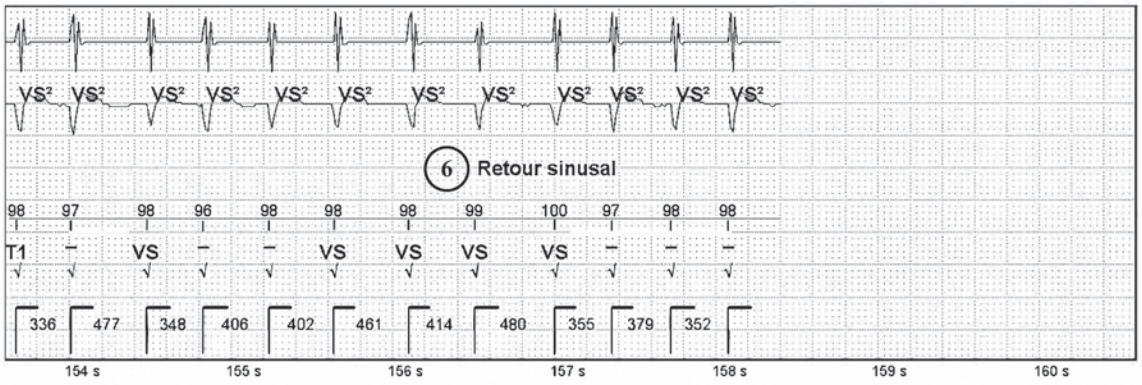
Épisode TV/FV 33 sur 44
Page 9 sur 9

8 févr. 2016 7:08

1: Ampli. Détect. V AutoGain (0,4 mm/mV) 3: Marqueurs
2: Discrimination AutoGain (0,8 mm/mV)

Vitesse de défilement : 25 mm/s



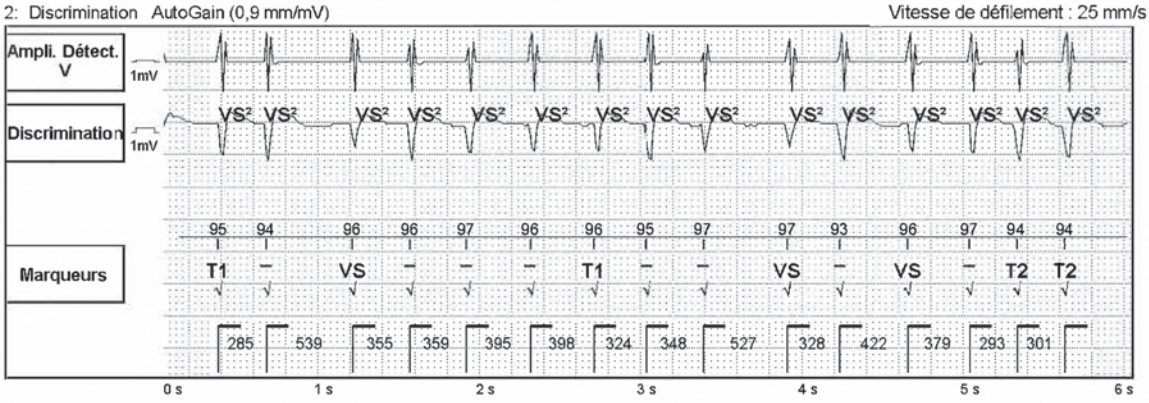


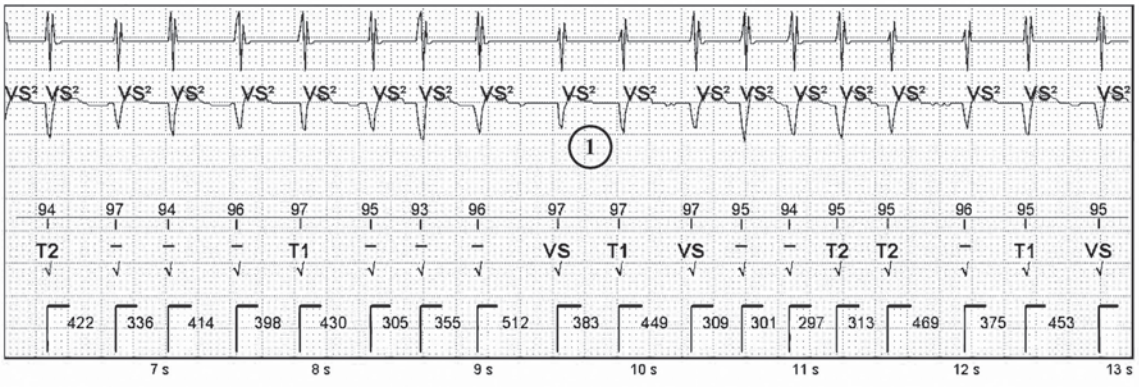
Episode: TSV (153 min^{-1} / 390 ms)

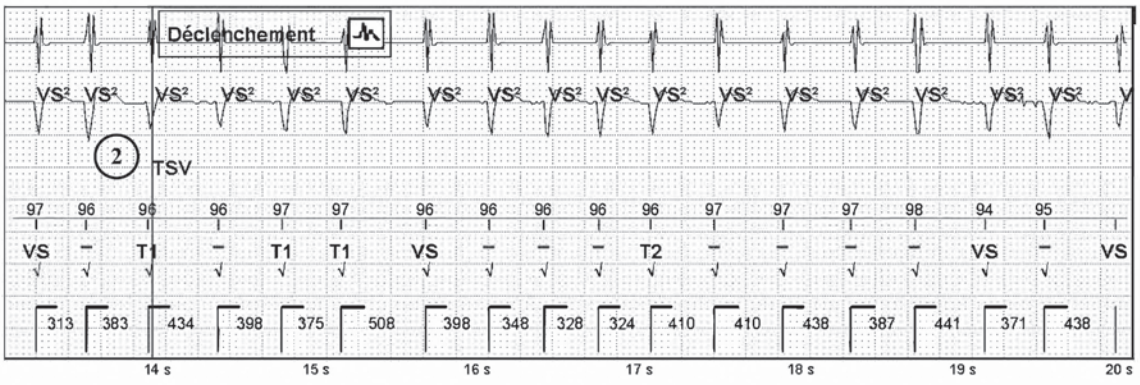
8 févr. 2016 6:26

1: Ampli. Détect. V AutoGain (0,4 mm/mV) 3: Marqueurs
2: Discrimination AutoGain (0,9 mm/mV)

Vitesse de défilement : 25 mm/s





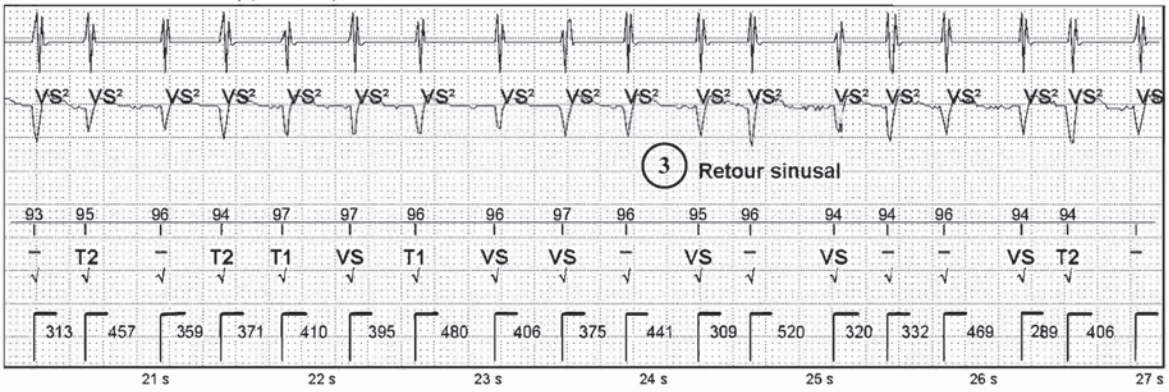


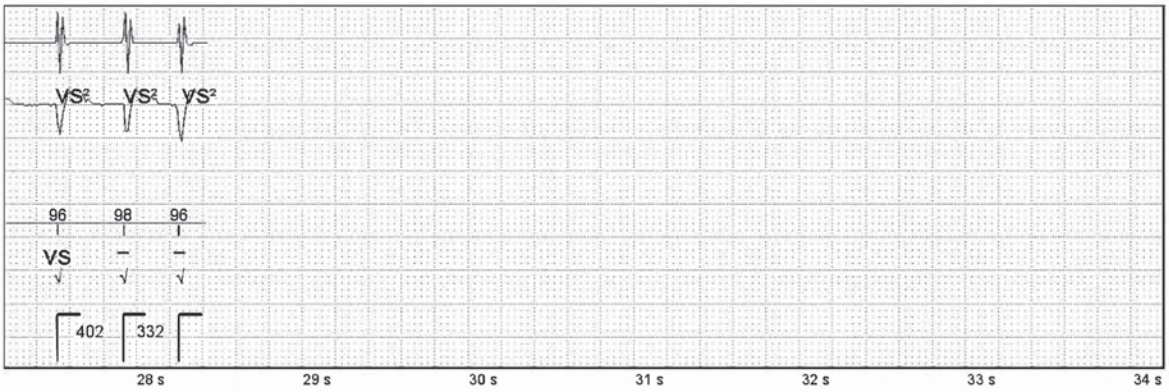
Episode: TSV (153 min-1 / 390 ms) (Continued)

8 févr. 2016 6:26

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,9 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s





ST. JUDE MEDICAL

À distance

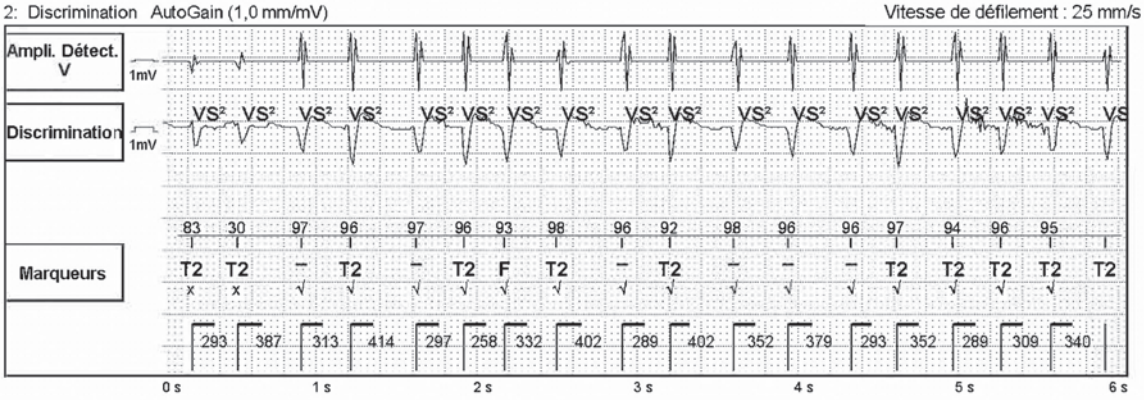
Episode: FV (218 min^{-1} / 275 ms)

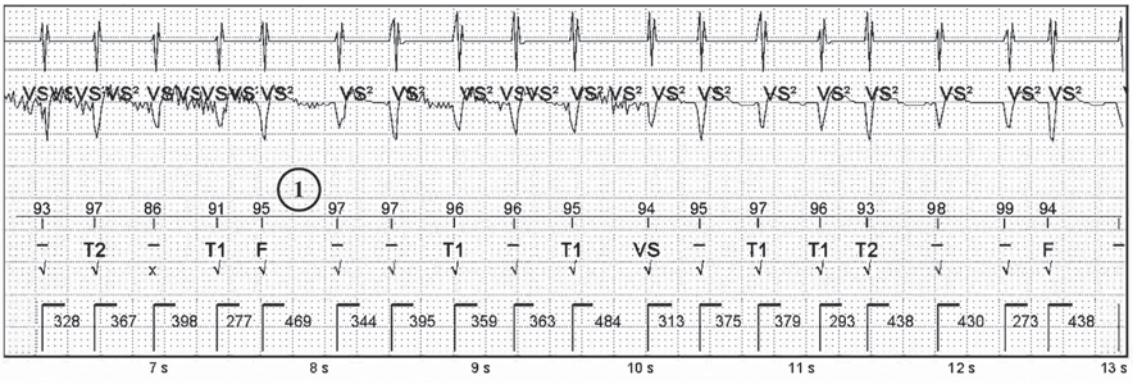
Épisode TV/FV 44 sur 44
Page 2 sur 6

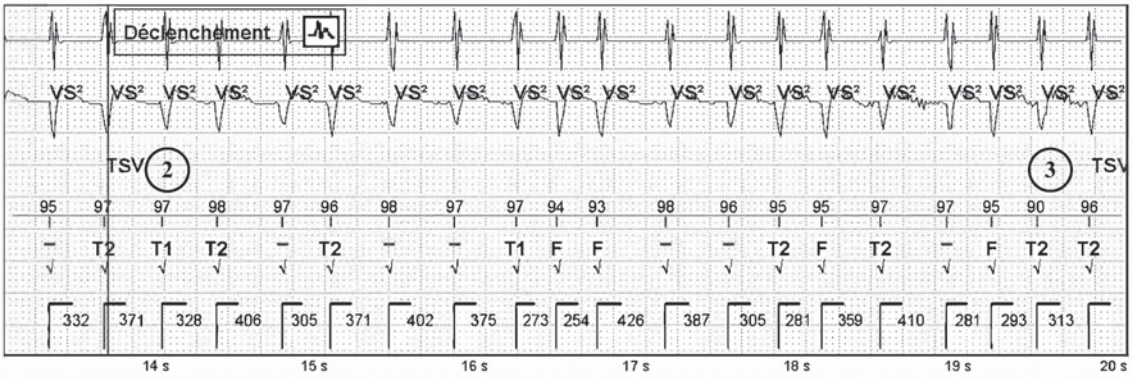
8 févr. 2016 7:30

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (1,0 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s







ST. JUDE MEDICAL

À distance

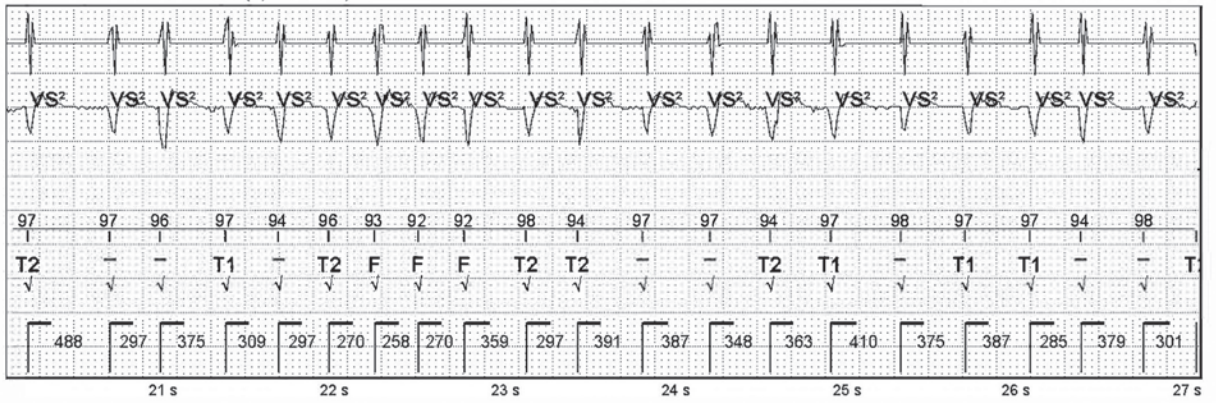
Episode: FV (218 min-1 / 275 ms) (Continued)

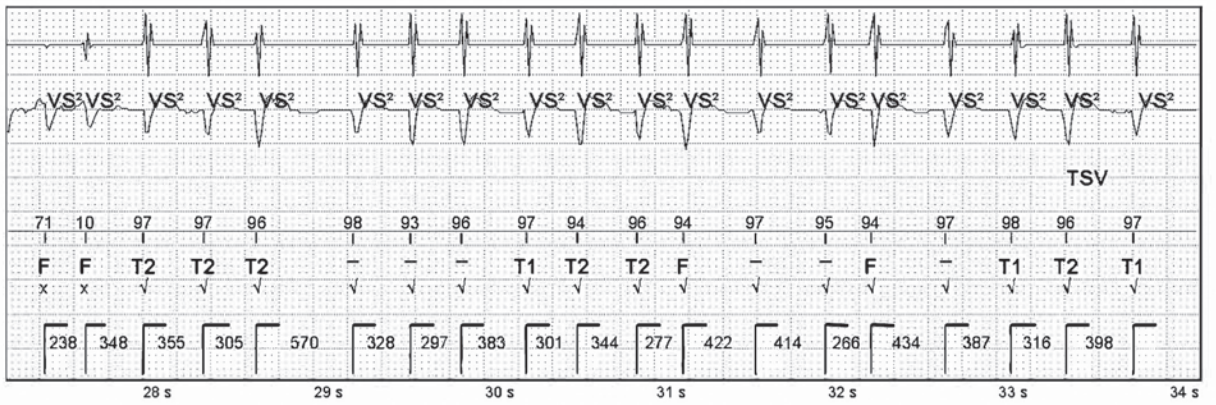
Épisode TV/FV 44 sur 44
Page 3 sur 6

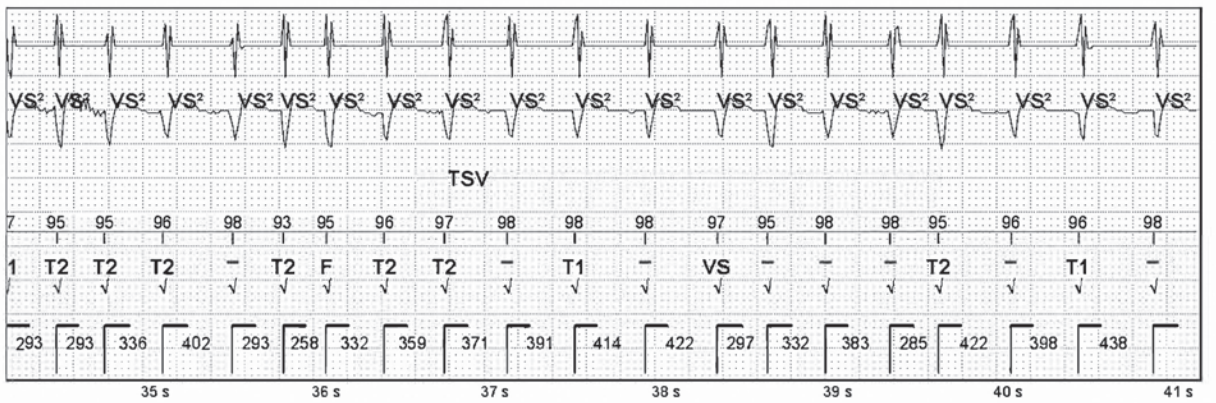
8 févr. 2016 7:30

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (1,0 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s







ST. JUDE MEDICAL

À distance

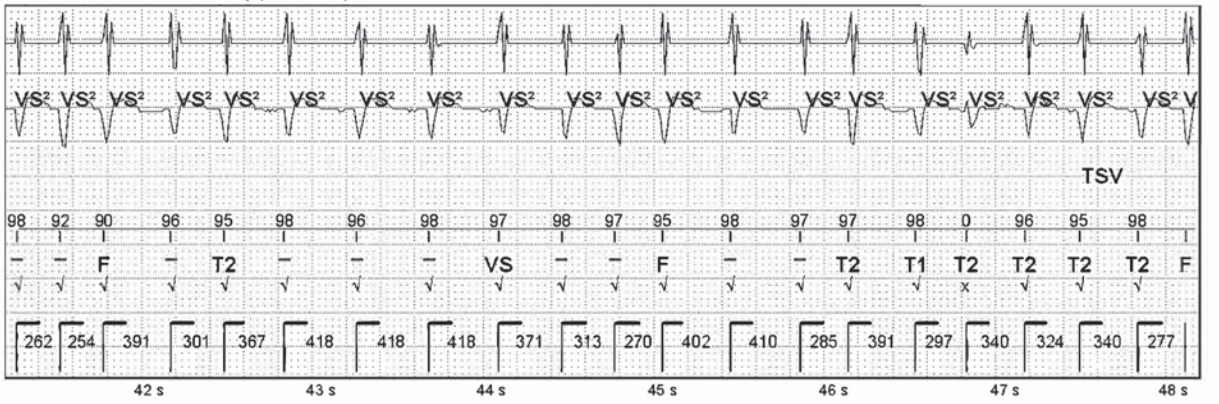
Episode: FV (218 min^{-1} / 275 ms) (Continued)

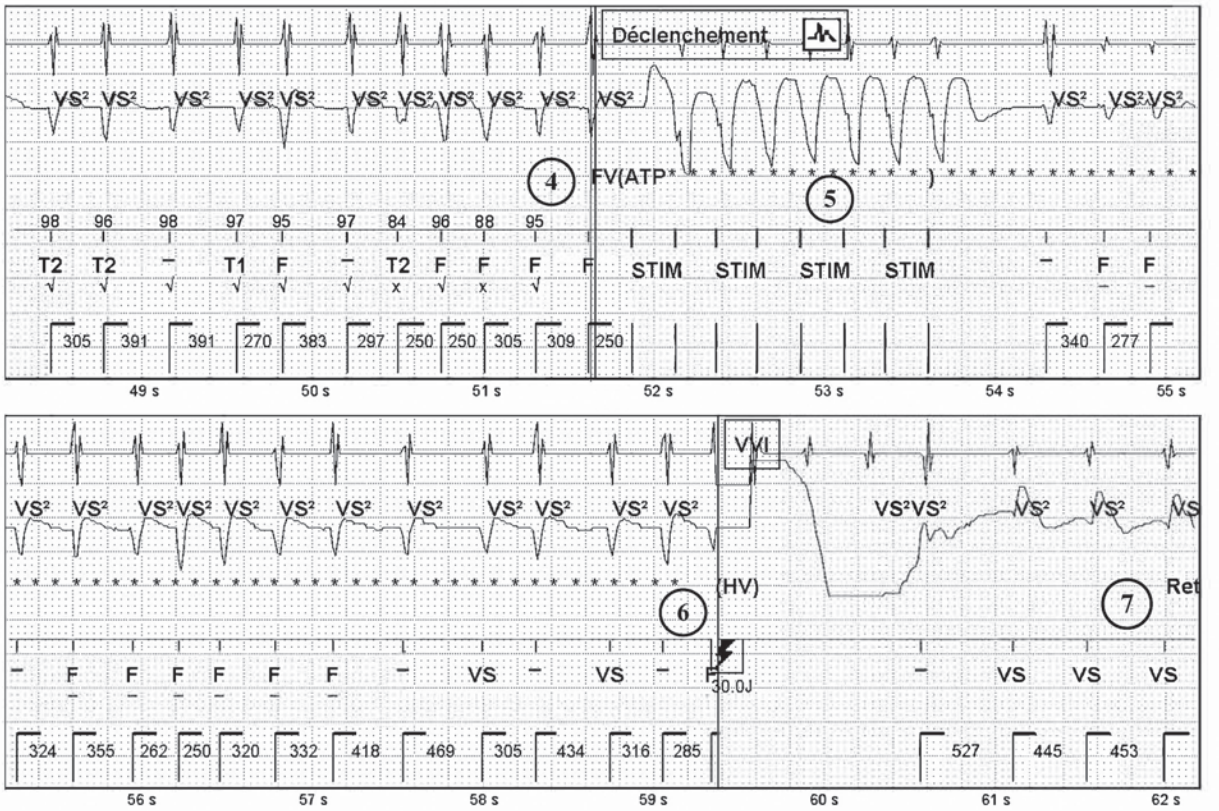
Épisode TV/FV 44 sur 44
Page 4 sur 6

8 févr. 2016 7:30

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (1,0 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s





ST. JUDE MEDICAL

À distance

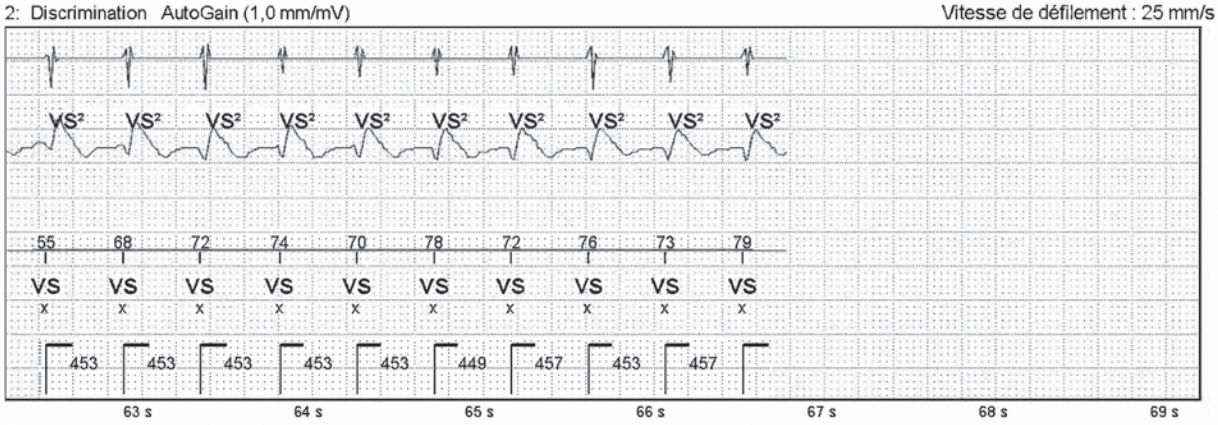
Episode: FV (218 min^{-1} / 275 ms) (Continued)

Épisode TV/FV 44 sur 44
Page 5 sur 6

8 févr. 2016 7:30

1: Ampli. Détect. V AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (1,0 mm/mV)
3: Marqueurs

Vitesse de défilement : 25 mm/s



Tracing 4: single chamber discrimination

Patient

This 66-year-old man received an Ellipse™ VR Saint Jude Medical ICD for the management of ischemic cardiomyopathy with depressed left ventricular ejection fraction. A remote monitoring message was transmitted for episodes of VT and SVT.

Tracing 4A

1: sinus tachycardia;
2: sudden onset of regular tachycardia; its morphology is visibly different from the sinus rhythm complexes despite a >90% similarity;
3: after 30 T classified cycles, the VT counter is full; diagnosis of SVT; while the sudden onset and stability criteria are in favor of VT, they did not contribute to the diagnosis since they were programmed on "passive"; the morphology criterion is in favor of SVT (the programmed threshold of similarity was >90%) and was the only criterion programmed ON;
4: the discrimination analysis is repeated every 6 T cycles; morphology consistent with SVT;
5: VT diagnosed when the similarity of morphology fell below 90%; a burst was delivered;
6: subtle acceleration of the rate followed by termination of tachycardia and diagnosis of return to sinus rhythm;

Tracing 4B

1: similar episode;
2: diagnosis of SVT;
3: diagnosis of SVT confirmed every 6 T classified cycles;
4: spontaneous termination after >23 minutes of poorly classified VT;

Comments

These tracings illustrate the limitations of a discrimination based solely on morphology. This patient presented with episodes of septal VT with a QRS morphology during tachycardia resembling sinus rhythm, which confused the morphology criterion and caused the erroneous diagnosis of SVT. The use of the sudden onset and stability criteria, on the other hand, would have allowed an accurate diagnosis of VT, had they not been programmed on "passive". This example illustrates the challenge represented by an optimal programming for all. This case might have been solved by one of two choices: 1) the nominal programming of the 3 criteria ON and a 2/3 setting, i.e. 2 criteria satisfied for a diagnosis of VT, or 2) increase of the percentage defining a similarity between reference and VT complexes from 90 to 95%. This percentage was below 95% in the clear majority of QRS complexes during VT and >95% of the complexes during sinus rhythm, thus offering a better sensitivity/specificity ratio.

ST. JUDE MEDICAL

14 Sep 2016
19:03
Archive

Episode: VT (210 bpm / 285 ms)

19 Aug 2016 7:40

Duration	00:22 (M:S)	**No Alerts**
Detection Criteria	171 - 221 bpm	

Therapy	**Results**
1) ATP	1) Below Rate Detection (CL 635 ms)

ATP Therapy Details
VT ATP Therapy

Successful BCL 244 ms
Therapy 1
Burst 1 244, 244, 244, 244, 244, 244, 244 ms

Diagnosis Summary

	Initial Diagnosis		Diagnosis	
	SVT		**VT**	
Time to Diagnosis			17,00 sec	
Rate (CL)	214 bpm (280 ms)		210 bpm (285 ms)	
Zone	VT			
Morphology	On, ≥ 90% is a match, ≥ 3 matches indicate SVT			
Min Match Score	91%		91%	
Max Non-Match Score	n/a		89%	
No. Template Matches	10 of 10	**(SVT Indicated)**	2 of 10	**(VT Indicated)**
Sudden Onset	Passive, < 20 % indicates SVT			
Max Delta	53 %	**(Passive: VT Indicated)**	53 %	**(Passive: VT Indicated)**
Interval Stability	Passive, ≥ 40 ms indicates SVT (SIH Passive, ≥ 2 intervals indicates SVT)			
Stability Delta	5 ms	**(Passive: VT Indicated)**	5 ms	**(Passive: VT Indicated)**
SIH Count	0	**(Passive: VT Indicated)**	0	**(Passive: VT Indicated)**

SVT Criteria Statistics
SVT Diagnoses during this episode 5

Measured SVT Discriminator values through initial VT/VF Diagnosis

Min Match Score	90 %	Min/Max Stability Delta	5 ms /10 ms
Max Non-Match Score	89 %	Min/Max SIH Count	0 / 0
Template Used	19 Aug 2016 4:58	Max Onset Delta	53 %

DeFT Response™ Settings (Shock Waveform)

			1st Phase	2nd Phase
Waveform	Biphasic	VF Shocks (Defib)	65 %	65 %
Waveform Mode	Tilt	VT Shocks (CVRT)	Same as Defib	Same as Defib
Shock Configuration	RV to Can			
RV Polarity	Anode(+)			
Defib Max Sensitivity	0.5 mV			

ST. JUDE MEDICAL

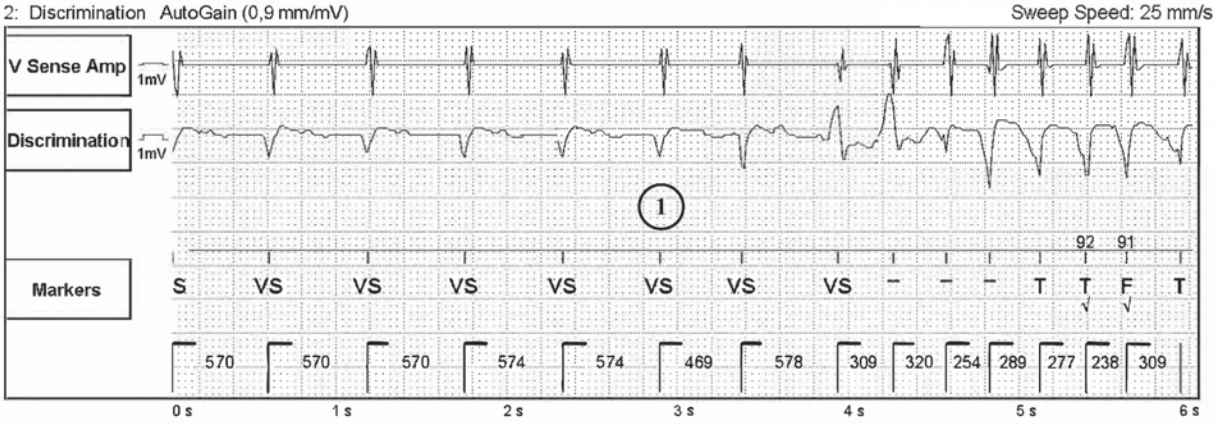
14 Sep 2016
19:03
Archive

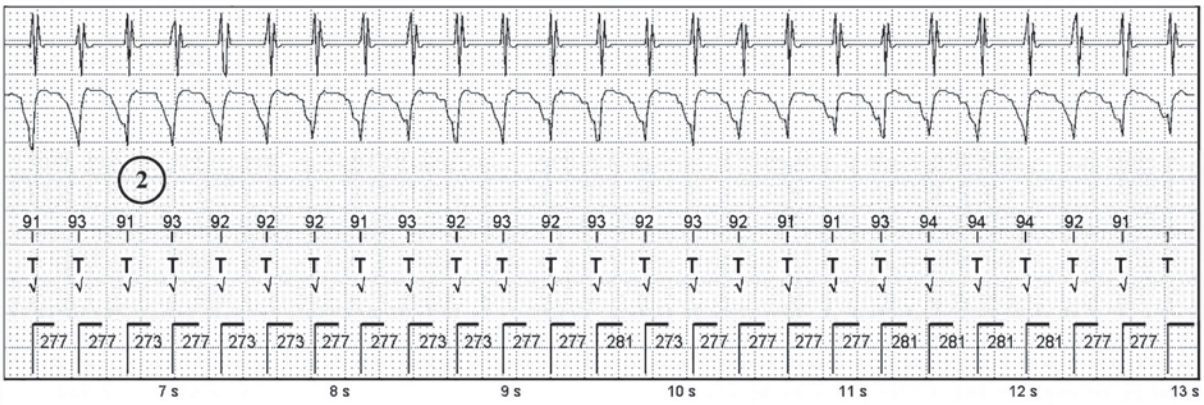
Episode: VT (210 bpm / 285 ms)

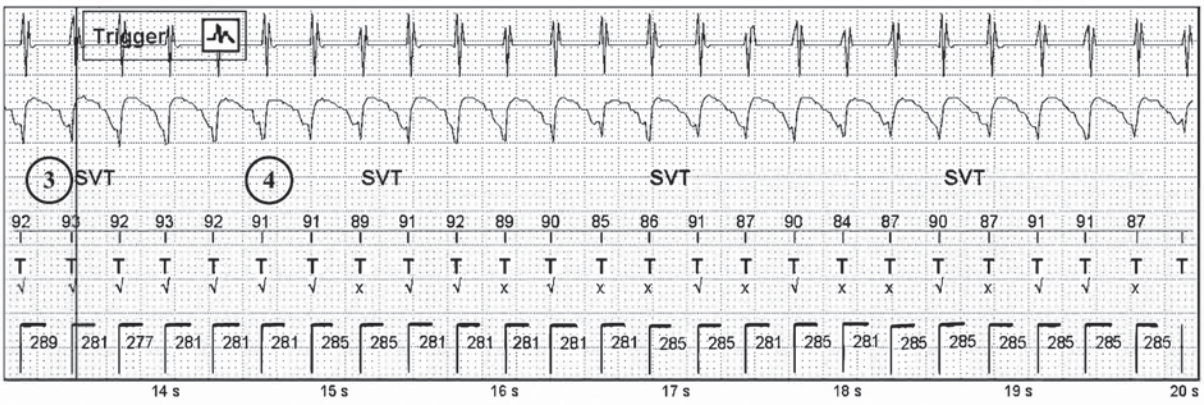
19 Aug 2016 7:40

1: V Sense Amp AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,9 mm/mV)
3: Markers

Sweep Speed: 25 mm/s







ST. JUDE MEDICAL

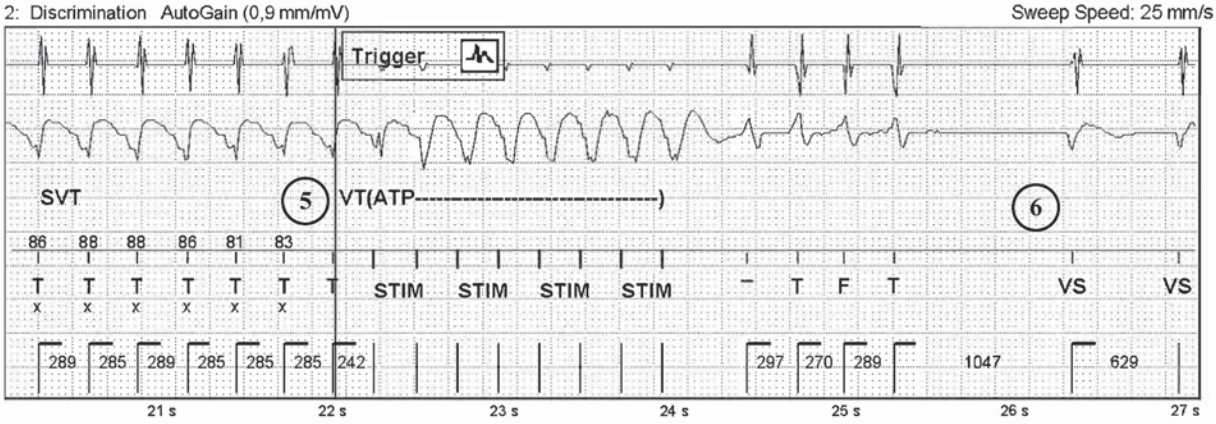
14 Sep 2016
19:03
Archive

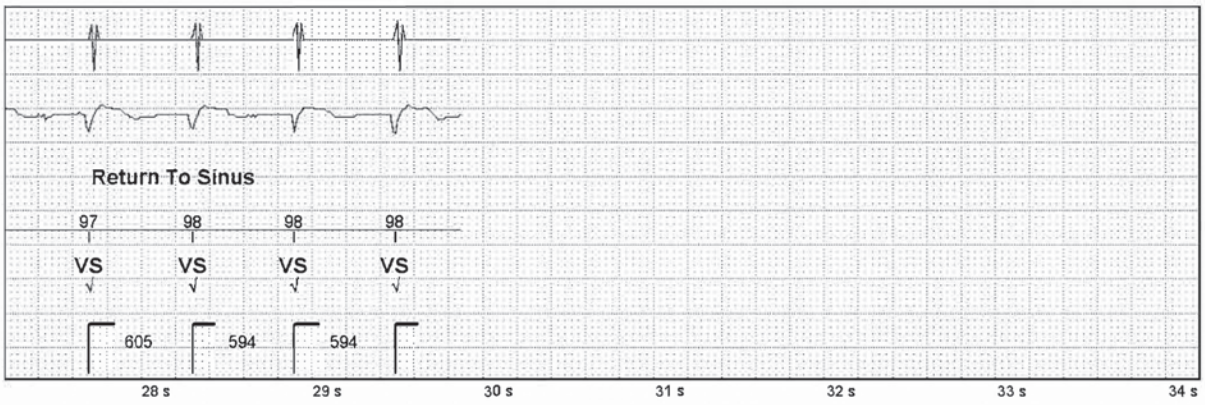
Episode: VT (210 bpm / 285 ms) (Continued)

19 Aug 2016 7:40

1: V Sense Amp AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,9 mm/mV)
3: Markers

Sweep Speed: 25 mm/s





ST. JUDE MEDICAL

14 Sep 2016
19:03
Archive

Episode: SVT (190 bpm / 315 ms)

19 Aug 2016 8:50

Duration	23:38 (M:S)	**Alerts**	**Duration over 1 minute**
Detection Criteria	171 - 221 bpm	⚠	

Therapy	**Results**
No therapies were delivered	

Diagnosis Summary

	Diagnosis
	SVT
Time to Diagnosis	9,00 sec
Rate (CL)	190 bpm (315 ms)
Zone	VT

Morphology	On, ≥ 90% is a match, ≥ 3 matches indicate SVT	
Min Match Score	92%	
Max Non-Match Score	n/a	
No. Template Matches	10 of 10	**(SVT Indicated)**
Sudden Onset	Passive, < 20 % indicates SVT	
Max Delta	53 %	**(Passive: VT Indicated)**
Interval Stability	Passive, ≥ 40 ms indicates SVT (SIH Passive, ≥ 2 intervals indicates SVT)	
Stability Delta	20 ms	**(Passive: VT Indicated)**
SIH Count	0	**(Passive: VT Indicated)**

SVT Criteria Statistics

SVT Diagnoses during this episode	255

Measured SVT Discriminator values for Episode

Min Match Score	90 %	Min/Max Stability Delta	0 ms /20 ms
Max Non-Match Score	89 %	Min/Max SIH Count	0 / 0
Template Used	19 Aug 2016 4:58	Max Onset Delta	53 %

DeFT Response™ Settings (Shock Waveform)			**1st Phase**	**2nd Phase**
Waveform	Biphasic	VF Shocks (Defib)	65 %	65 %
Waveform Mode	Tilt	VT Shocks (CVRT)	Same as Defib	Same as Defib
Shock Configuration	RV to Can			
RV Polarity	Anode(+)			
Defib Max Sensitivity	0.5 mV			

ST. JUDE MEDICAL

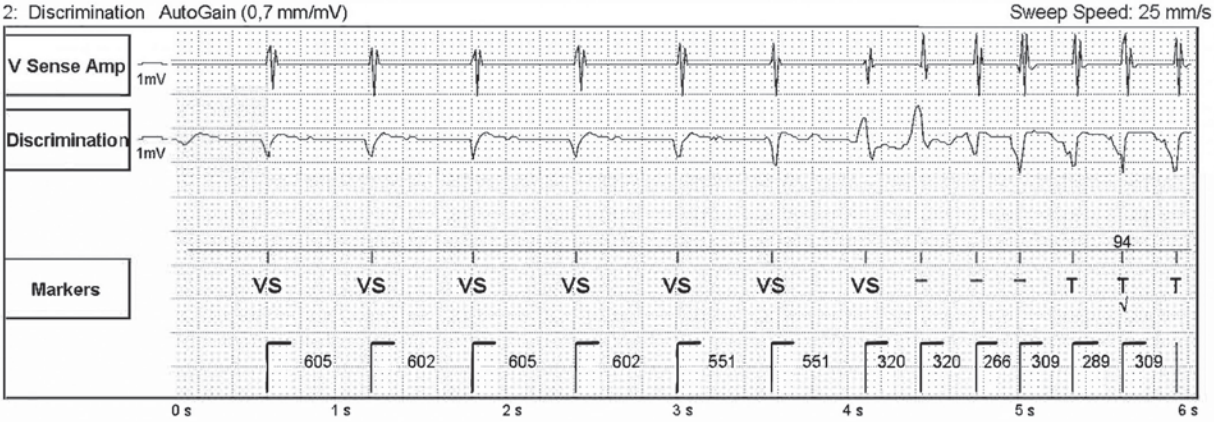
14 Sep 2016
19:03
Archive

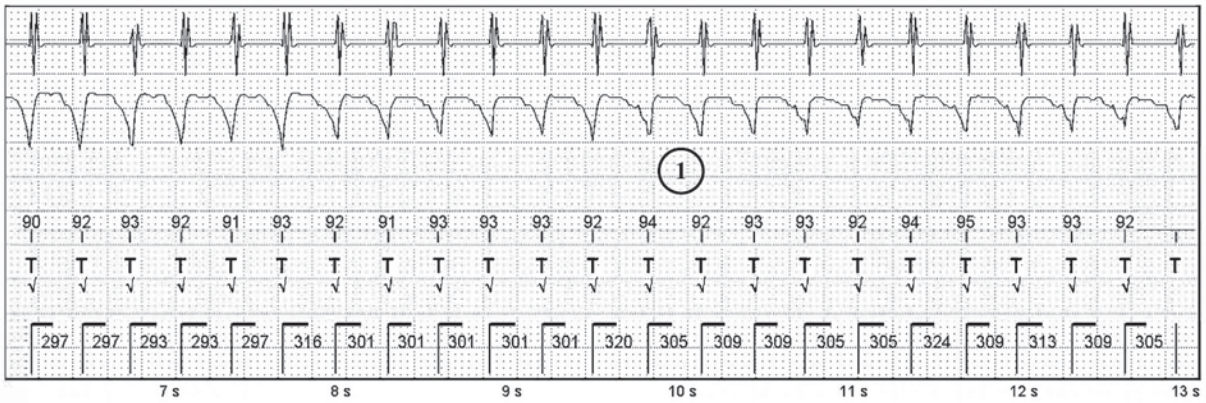
Episode: SVT (190 bpm / 315 ms)

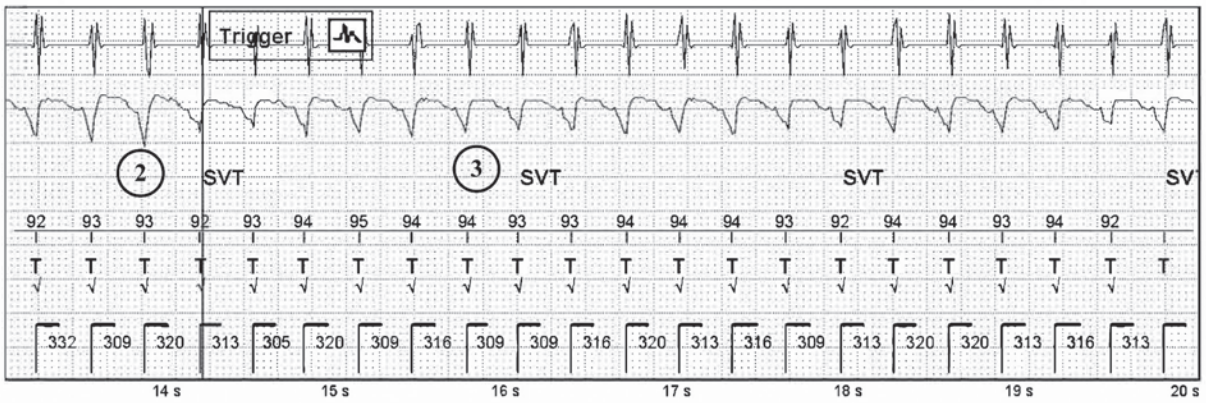
19 Aug 2016 8:50

1: V Sense Amp AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,7 mm/mV)
3: Markers

Sweep Speed: 25 mm/s







ST. JUDE MEDICAL

14 Sep 2016
19:03
Archive

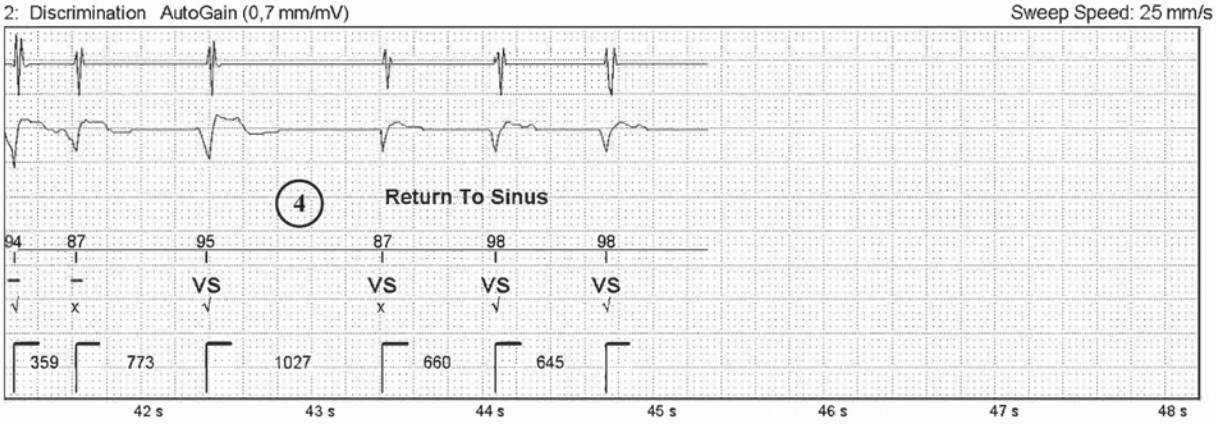
Episode: SVT (190 bpm / 315 ms) (Continued)

19 Aug 2016 8:50

VT/VF Episode 20 of 20
Page 4 of 4

1: V Sense Amp AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,7 mm/mV)
3: Markers

Sweep Speed: 25 mm/s



Chapter 2

SecureSense™ algorithm

SecureSense™ Algorithm

Introduction

The last consensus of experts on the optimization of ICD programming recommends, in recipients of Saint Jude Medical devices, the systematic programming of the SecureSense™ algorithm. This algorithm was initially conceived to enable an early diagnosis of ICD lead dysfunction, the weak link of defibrillation systems. Partial conductor or insulator fractures and connection issues modify infrequently the pacing and defibrillation impedance or the measurements of pacing and sensing threshold. Consequently, a follow-up based exclusively on these measurements is often associated with a belated diagnosis of lead dysfunction that can be the source of inappropriate therapies. On the other hand, the occurrence of brief, characteristic episodes of ventricular oversensing (intermittent sensing of short, disorganized, non-physiologic cardiac signals) is often an early sign of lead dysfunction. These signals are highly variable in amplitude and rate, and may saturate the amplifiers (conductor break). In the early phase of a lead or insulator rupture, oversensing may be limited to the bipolar sensing channel and be absent on the high-voltage channel. The functional principle of the SecureSense™ algorithm is based on this discordance and on a comparison between the bipolar sensing channel and the "discrimination channel". A noise counter increases when short cycles are limited to the bipolar channel and are absent on the discrimination channel. When oversensing is suspected, the therapies are inhibited and an alert (vibration of the pulse generator and/or remote monitoring alert) is triggered to prompt an expeditious intervention. The algorithm combines a protection against undersensing on the discrimination channel, to guarantee the highest safety, and an optimal ability to detect ventricular arrhythmias. The SecureSense™ algorithm was originally conceived to diagnose noises originating from the lead, caused by a) a fracture of the pacing or sensing conductors, b) an insulator rupture, or c) an insufficient tightening or a faulty insertion of the lead connector in its receptacle. This algorithm seems highly promising by allowing also the diagnosis of other types of oversensing (P and T waves, double counting of the R wave) and by eliminating inappropriate therapies in this context.
This chapter explains the broad principles followed by the functional details of this algorithm and by illustrative tracings.

Functional principles of the SecureSense™ algorithm

The SecureSense™ algorithm interferes directly with the decision, by the implantable device, to treat or not treat a rapid episode, including a range of very rapid rates that threaten the patient's prognosis, as it operates in the VT as well as in the VF zones. The main objective of this algorithm is to increase the device's specificity by inhibiting inappropriate therapies that might be delivered because of oversensing. It is, consequently, of foremost importance that the highest sensitivity is preserved, and that all episodes of sustained ventricular arrhythmia be effectively diagnosed and appropriately treated.
The SecureSense™ algorithm is based on 6 broad functional principles:
1) it is based on an analysis of the congruence of the length of the ventricular cycles present on the bipolar and the discrimination channels. A noise counter is integrated in the decision to deliver or inhibit the therapies. Once active, it increases with each short cycle sensed by the bipolar channel, and is reset to 0 after 2 short cycles sensed by the discrimination channel;
2) the algorithm suspects oversensing and inhibits the therapies, should a discordance between the 2 channels be detected, i.e. the presence of short cycles on the bipolar channel, which increase the arrhythmia counter, in absence of short cycles on the discrimination channel;
3) the algorithm suspects a true ventricular arrhythmia and does not inhibit the programmed therapies when both channels are concordant: i.e. short cycles are detected on the bipolar channel as well as on the discrimination channel;
4) the algorithm diagnoses non-sustained episodes of noise when the noise counter increases without saturating the arrhythmia counter; this allows the identification of oversensing issues, even when sporadic;

5) a protection has been put in place against the risk of inhibition of the therapies in presence of undersensing by the discrimination channel, which is indispensable to preserve the highest sensitivity of the device to diagnose ventricular arrhythmias;
6) this algorithm operates together with the programming of patient warnings (vibrations of the pulse generator) and remote monitoring alerts (Merlin.net™), which shorten the delay between the diagnosis of oversensing by the device and its medical management.

Details of the SecureSense™ algorithm function

The discrimination channel

This channel is used for the SecureSense™ algorithm as well as to optimize the discrimination between arrhythmias of ventricular versus supraventricular origin. Sensing in the discrimination channel may take place between the RV coil and the pulse generator (coil to can) or between the RV distal electrode (tip to can) and the can (programmable configuration). It is, therefore, in both instances, a «unipolar» or «far-field» sensing (with a single pole inside the heart). In nominal programming, the discrimination channel senses between the coil and the can. It is noteworthy that, while the distal electrode (tip) - can configuration may be a tempting means of discriminating the origin of arrhythmias, it should probably be omitted in order to detect lead breakdowns reliably. Since the distal electrode is common to both channels that are being compared, a dysfunction of that electrode may become apparent as short cycles oversensed on both the high voltage and the discrimination channels (resetting of the noise counter to 0 leading to an absence of inhibition of the therapies).

Sensing in the discrimination channel and automatic control of sensitivity

Like the bipolar channel, the discrimination channel operates with an automatic adaptive sensitivity: instead of a fixed value, the sensing threshold adapts automatically, according to the amplitude of the preceding R wave, with the level of sensitivity increasing thereafter throughout the cycle, until it reaches the lowest programmed value (maximum sensitivity) in search of a possible low-amplitude signal. The main difference with respect to the bipolar channel is the total absence of programmable settings: the post-sensing ventricular refractory period measures 150 ms, the threshold start is at 62.5% without decay delay, the maximal sensitivity is 0.3 mV and the low-frequency attenuation filter is deactivated.

Parameter	Bipolar RV Channel	Discrimination Channel
Threshold Start	50%	**62.5%**
Decay Delay	60 ms	0 ms
Max Sensitivity	0,5 mV	0,3 mV
Sense ventr. refractory period	125 ms	**150 ms**
Ventricular Blanking	52 ms	52 ms (44 ms if AP < 2,5 V)
Slope	1 mV / 312 ms	1 mV / 312 ms
Low Frequency Attenuation	On	Off
Warm up	No	**Yes – 350 ms**
Programmable	Yes	**No**

Markers and intervals on the discrimination channel

The number 2 of the marker VS2 corresponds to a sensed event in the second sensing channel. Whether the cycle is short (tachycardia) or long (slow rhythm), all signals sensed in the discrimination channel are marked VS2 (no VS, -, VF or VT marker). The intervals between 2 VS2 cycles are not marked on the tracing, which may on occasion complicate the explanation of the algorithm function.

Activation of the noise counter on the discrimination channel

Sensing on the SecureSense™ discrimination channel is not constantly activated (which would slightly increase the power consumption of the device). The noise counter is automatically activated after the detection, on the bipolar channel, of 2 out of 3 instantaneous cycles corresponding to the VT or the VF zones. Because of the presence of a 350-ms warm-up interval during which sensing is precluded, sensing on the discrimination channel begins 350 ms after the second short cycle on the bipolar channel.

Deactivation of the noise counter on the discrimination channel

Once the noise counter activated, it increases with each short cycle on the bipolar channel and is deactivated only after 255 intervals classified VS or VP. Two out of three short cycles are needed to reactivate the counter.

The noise counter

Once activated, the counter is incremented after the occurrence of short cycles on the bipolar channel: the noise counter is incremented by 1 with each detection of an instantaneous short interval on the bipolar channel; a short cycle on the bipolar channel may correspond to a F, T or - marker if the instantaneous cycle is short and the average of the 4 preceding cycles is long.
The counter is reset to zero after the occurrence of short cycles on the discrimination channel: the noise counter is reset to zero after the detection of 2 short instantaneous cycles on the discrimination channel; these cycles do not need to be consecutive. The definition of a "short" cycle on the discrimination channel varies as a function of the number of programmed zones. In presence of a single programmed VF zone, a cycle is short if <400 ms. In presence of one or two programmed VT zones, a cycle is short if shorter than the longest programmed VT cycle +50 ms (if for example, the VT zone 2 is programmed between 350 and 270 ms and VT zone 1 between 420 and 350 ms, a cycle is short if ≤470 ms).

Noise counter and delivery of therapies

When the VT or VF counter is full, the analysis of the noise counter has a direct influence on the decision to deliver or withhold the delivery of therapy:
- if the noise counter is <10: a) the VT/SVT discrimination scrutinizes the VT zone before delivering a first therapy; b) the first therapy is delivered in the VF zone if it consists of ATP delivered before or during the charge. If the ICD's capacitors are being charged, the noise counter is verified one more time at the end of the charge and, if <10 the shock is delivered whereas if it is ≥10 it is dumped. Once a first therapy delivered, the SecureSense™ algorithm is withheld until the end of the episode, i.e. until the return to sinus rhythm.
- if the noise counter is ≥10 when the VT or VF counter is full, oversensing is diagnosed and the therapies are inhibited. The count of SecureSense™ is verified with each redetection of VT or VF (every 6 cycles). If the counter remains ≥10, the therapies are inhibited.

Noise counter and non-sustained oversensing

Once activated, the noise counter increases continuously in presence of intermittent short cycles detected on the bipolar channel. If the short cycles are intermittent, the VT or VF counter never fills up. However, if the noise counter reaches a count of 10 (5 on the early models) or a multiple of 10, a non-sustained lead noise is diagnosed and a marker (SNS on the new models) is inscribed on the tracing. An alert and a patient notification may also be delivered.

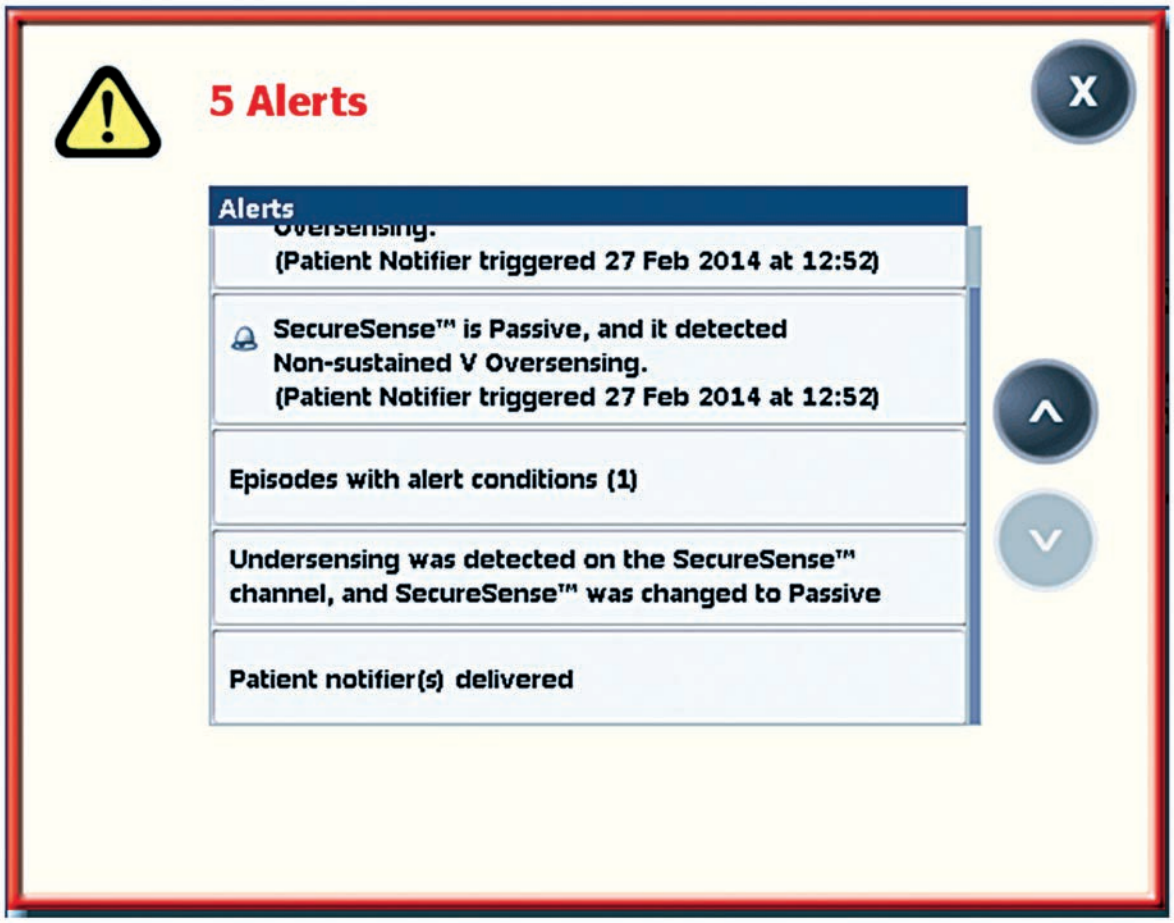
Protection against undersensing

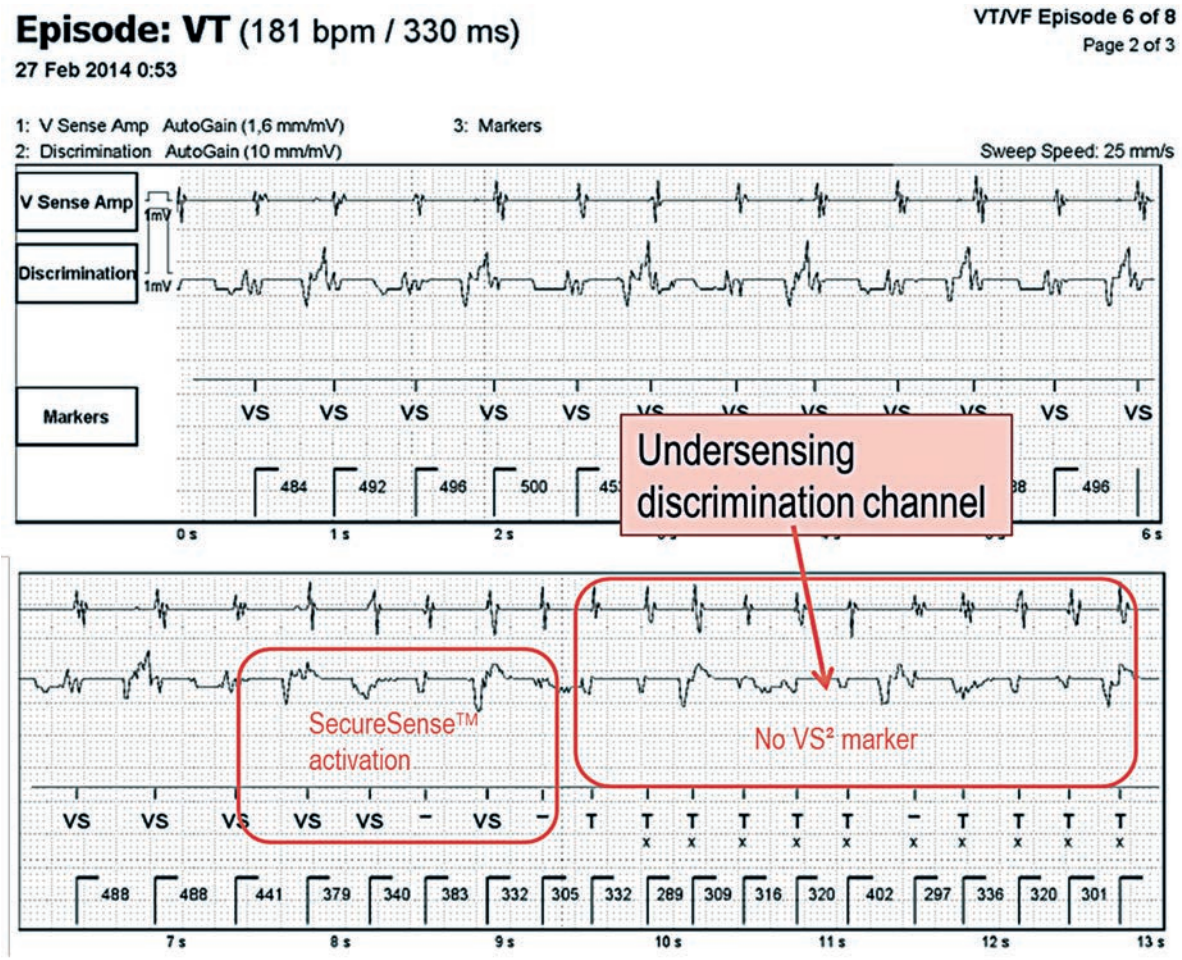
To preserve the highest sensitivity and lower the risk of inhibiting the therapies due to undersensing on the discrimination channel, the algorithm incorporates a protection, which cancels the inhibition of therapies, should sensing on this channel be flawed. The algorithm is automatically reprogrammed to "Passive" during the episode, enabling the delivery of therapy. The algorithm is interrupted if one of these three events occurs during an episode: 1) ≥2 VS2 cycles with a <0.6 mV amplitude, 2)

a pause > 2200 ms between two VS2 cycles, or 3) occurrence of a single cycle on the discrimination channel during the tachycardia. This protection prevents the inhibition of therapies by prolonged undersensing of an actual VT or VF on the discrimination channel. If the algorithm is interrupted, a specific warning of undersensing on the discrimination channel is notified on the programmer at the time of interrogation.

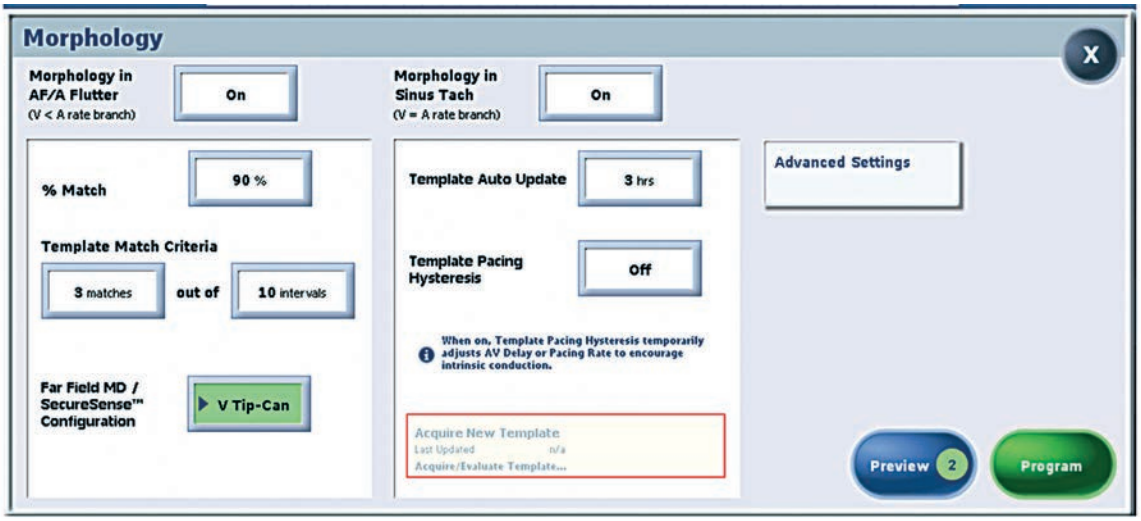
Protection against undersensing

To preserve the highest sensitivity and lower the risk of inhibiting the therapies due to undersensing on the discrimination channel, the algorithm incorporates a protection, which cancels the inhibition of therapies, should sensing on this channel be flawed. The algorithm is automatically reprogrammed to "Passive" during the episode, enabling the delivery of therapy. The algorithm is interrupted if one of these three events occurs during an episode: 1) ≥2 VS2 cycles with a <0.6 mV amplitude, 2) a pause between two >2,200-ms VS2 cycles, or 3) occurrence of a single cycle on the discrimination channel during the tachycardia. This protection prevents the inhibition of therapies by prolonged undersensing of an actual VT or VF on the discrimination channel. If the algorithm is interrupted, a specific warning of undersensing on the discrimination channel is notified on the programmer at the time of interrogation.

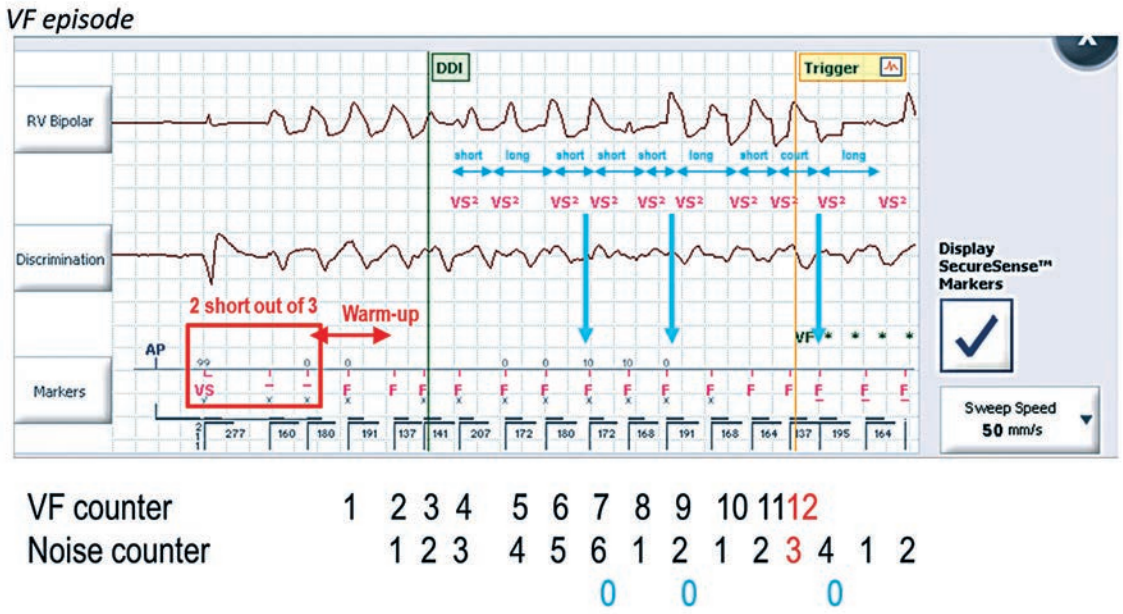




To optimize the detection in the discrimination channel, the RV coil – can configuration can be reprogrammed to V tip-can. This sensing vector, however, may present limitations from the standpoint of prevention of inappropriate therapies due to lead fracture.

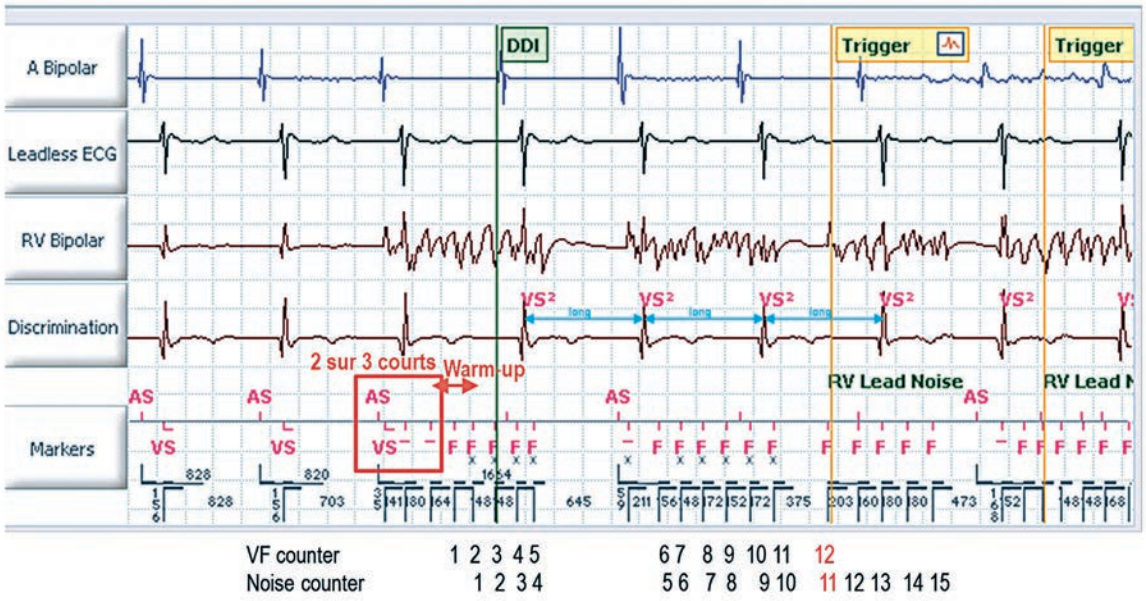


Examples of device function



The bipolar and the discrimination channels show concordant short cycles and EGM characteristic of polymorphous tachycardia. The noise counter is activated after 2 instantaneous short cycles (classified -) on the bipolar channel + 350 ms (corresponding to the warm-up phase), followed by the appearance of the VS2 markers on the discrimination channel. The VF counter increases with each F-classified cycle and is filled when its programmed value reaches 12. The noise counter increases in parallel, with each short cycle on the bipolar channel, though is reset to 0 each time 2 short, not necessarily consecutive cycles, are detected on the discrimination channel. When the VF counter is full (12), the noise counter is 3, thus well below 10. This confirms that the episode is true VF, the therapies are not inhibited and the capacitors are charging. At the end of charge, the noise counter is, once again, verified.

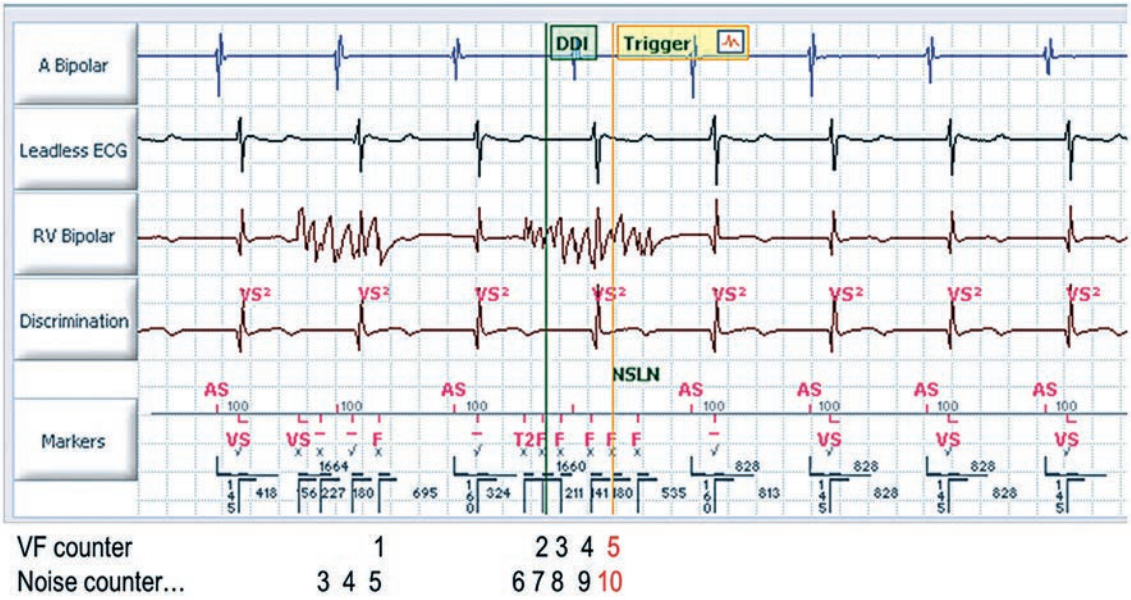
Oversensing due to lead fracture



There is a characteristic discordance between the bipolar channel, where the cycles are short and disorganized, and the discrimination channel, which shows an unremarkable tracing. The noise counter is activated after 2 instantaneous short cycles (classified -) on the bipolar channel + 350 ms

(corresponding to the warm-up phase). The first VS2 marker appears thereafter on the discrimination channel at the time of the next QRS complex. The VF counter increases with each F-classified cycle (multiple oversensing); it is full when it reaches the programmed value of 12. The noise counter increases in parallel with each short cycle on the bipolar channel. This counter is never reset to 0 since no short cycle is present on the discrimination channel. When the VF counter is filled (12), the noise counter is above or equal to 10 (11). The device diagnoses oversensing (RV lead noise) and inhibits the therapies. After each redetection (6 F-classified cycles) on the bipolar channel, the noise counter undergoes a new analysis. If, as in this example, the counter remains ≥10, the therapies are inhibited since the device has diagnosed persistent oversensing.

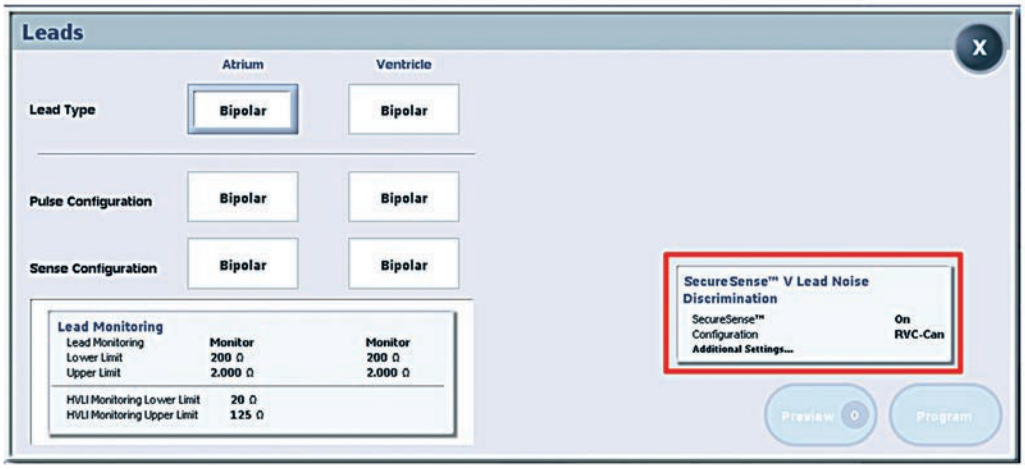
Episode of non-sustained oversensing



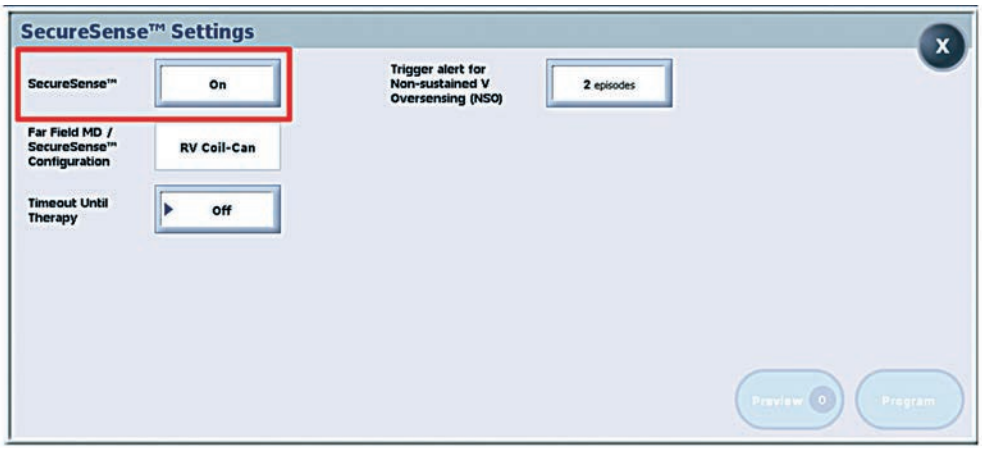
The same characteristic aspect of oversensing is apparent, with short cycles present on the bipolar channel and absent on the discrimination channel (the QRS complexes are accurately sensed). The episodes of oversensing are brief and the VF counter is never filled, while the noise counter has reached 10. The noise counter is never reset to 0 since there is no short cycle on the discrimination channel. An episode of non-sustained oversensing (NSLN, NSN on the new devices) is diagnosed. The NSLN or NSN marker appears thereafter on the tracing each time the noise counter reaches a multiple of 10. A remote monitoring alert is triggered after a programmable number of similar non-sustained episodes of noise. This algorithm, therefore, discloses the occurrence of oversensing issues, including when they are highly intermittent, representing an important contribution to an early diagnosis of lead dysfunction, which often manifests itself initially as very brief episodes of short ventricular cycles.

Programming the SecureSense™ algorithm

The SecureSense™ algorithm, which is activated by default, may be programmed on the "Leads" screen of the "Bradycardia" menu, as well as on the main screen of the "Tachycardia" menu.



It offers 4 programmable items:



1. The mode

The 3 choices available are ON, PASSIVE and OFF.
ON: episode of sustained noise: inhibition of the therapies, patient warning (vibration) and remote monitoring alert; episode of non-sustained noise: patient warning (vibration) and remote monitoring alert; the various EGM are recorded in the memories.
Passive: episode of sustained noise: the therapies are not inhibited, patient warning (vibration); episode of non-sustained noise: patient warning (vibration); the various EGM are stored in the memories.
OFF: the therapies are not inhibited; episodes of sustained or non-sustained noise are not recorded.

2. The discrimination channel

Two choices are available: RV Coil – Can by default, or V tip – can.

3. Timeout until therapy

One can program a timer to limit the maximum duration of inhibition of the therapies. If the device diagnoses a sustained noise and inhibits the therapies in a first step, the therapies are delivered at the end of the timing if the noise persists.

4. The number of non-sustained episodes needed to trigger an alert

A single sustained episode with inhibition of the therapies suffices to prompt a patient warning and a remote monitoring alert. The number of non-sustained episodes, on the other hand, is programmable.

Tracing 1: SecureSense™ algorithm during a VF episode

Patient

This 80-year-old man presenting with an ischemic cardiomyopathy and a 35% left ventricular ejection fraction had undergone implantation of a Saint Jude Medical Fortify Assura™ VR ICD. He was seen after an episode of syncope during which he received an electric shock; the SecureSense™ algorithm was programmed ON with a RV coil to can configuration; 2 zones of detection were programmed i.e. VF at 222 bpm (270 ms cycle length) and VT at 166 bpm (360 ms cycle length).

Tracing

1: slow and irregular baseline rhythm consistent with AF and a slow ventricular response;
2: premature ventricular contraction triggering an episode of fast ventricular arrhythmia;
3: ventricular sensing with non-classified (-) cycle because of discordance between the instantaneous interval (short cycle consistent with the VF zone) and the average of 4 cycles (consistent with the sinus zone);
4: second, short, F-classified cycle (concordance between instantaneous interval and the average of 4 cycles); after the detection of this second short cycle on the bipolar channel, activation of the noise counter on the discrimination channel (begins after an additional warm-up of 350 ms);
5: T-classified cycle without VS2 marker on the discrimination channel despite a visually tall amplitude, because the signal fell in the warm-up phase;
6: persistence of the ventricular arrhythmia; first VS2 cycle on the discrimination channel;
7: signal sensed on the bipolar and not on the discrimination channel (intermittent undersensing on this channel);
8: resumption of sensing on both channels;
9: each short cycle on the bipolar channel increases the noise counter; however, this noise counter is reset to 0 after 2 short cycles on the discrimination channel (on this channel, a cycle is short if <360+30=390 ms);
10: systematic resetting of the noise counter to 0 after 2 short cycles on the discrimination channel;
11: the VF counter is filled (12); since the noise counter is <10, the therapies are not inhibited by the algorithm;
12: ATP during the charge; 8 stimuli are delivered at a fixed rate while the capacitors are charging;
13: unsuccessful ATP and continuation of fast, polymorphous VT;
14: end of charge (36 J);
15: electric shock delivered;
16: 1-second post-shock blanking;
17: successful electric shock and interruption of the tachycardia; it is noteworthy that, for this cycle, the discrimination channel oversenses, illustrating the limitations of this channel after the delivery of a shock (distortion of the signal), explaining the interruption of the algorithm after a first therapy;
18: return to sinus rhythm diagnosed after 3 consecutive VS-classified cycles;

Comments

This tracing illustrates characteristic aspects of the SecureSense™ algorithm function during a ventricular arrhythmia:
1) the noise counter is not constantly activated. When it is inactive, the VS2 markers are missing on the discrimination channel. The activation of this counter requires 2 instantaneous cycles out of 3 corresponding to the VT or VF zone. The second cycle is followed by a 350-ms interval during which this channel cannot sense. This explains, during this episode, the absence of VS2 marker on the discrimination channel corresponding to the T cycle following the second short cycle.
2) during an episode of ventricular arrhythmia, the occurrence of short cycles on the discrimination channel prevents increases in the noise counter, which is reset to 0 each time 2 short cycles are

detected, even if they are not consecutive. The definition of a short cycle on the bipolar versus on the discrimination channel is different. On the latter, it depends on the number of zones of tachycardia programmed and their rate limits (30 ms above the limit of the lowest zone, if 2 or 3 zones have been programmed). In this patient, the threshold defining a short cycle on the discrimination channel is, therefore, 360 + 30 ms = 390 ms.
3) in the beginning of the tracing, a cycle was not detected on the discrimination channel, which has no effect on the final analysis of the episode. A moderate amount of undersensing interferes minimally with the function of the algorithm, since the number of short cycles remains high and reinitializes often the counter.
4) in this example of fast, polymorphous VT, multiple short cycles are detected on the discrimination channel, and the noise counter is constantly reset to zero. During an episode of VT or VF, if the discrimination channel detects accurately, the device observes a concordance between the 2 analyzed channels and detects short cycles consistent with an arrhythmia. When the VF counter is filled, the SecureSense™ counter is <10 and the therapies are delivered. The next tracings show a protection against undersensing, which limits the risk of inappropriate inhibition of the therapies for ventricular arrhythmia.
5) after an electric shock, oversensing may appear on the discrimination channel because of a poor quality of the signal. After delivery of the therapy the SecureSense™ algorithm remains inactive until the next return to sinus rhythm has been diagnosed.

ST. JUDE MEDICAL

13 Aug 2013
13:29
Archive

Episode: VF (230 bpm / 260 ms)

VT/VF Episode 2 of 3
Page 1 of 3

11 Mar 2013 18:18

Duration	00:18 (M:S)	**No Alerts**
Detection Criteria	222 bpm	

Therapy	**Results**
1) ATP x 1	1) VF
2) Defib 36,0 J (844V)	2) Below Rate Detection (CL 825 ms)

HV Therapy	
Last HV Lead Impedance	73 Ω
Last Charge Time	8,3 sec
Delivered PW	+8,1 ms, -8,1 ms

ATP Therapy Details
VF ATP Therapy

Therapy
Burst 1 224, 224, 224, 224, 224, 224, 224 ms

Diagnosis Summary

	Diagnosis
	VF
Time to Diagnosis	3,00 sec
Rate (CL)	230 bpm (260 ms)

DeFT Response™ Settings (Shock Waveform)			**1st Phase**	**2nd Phase**
Waveform	Biphasic	VF Shocks (Defib)	65 %	65 %
Waveform Mode	Tilt	VT Shocks (CVRT)	Same as Defib	Same as Defib
Shock Configuration	RV to Can			
RV Polarity	Anode(+)			
Defib Max Sensitivity	0.5 mV			

ST. JUDE MEDICAL

13 Aug 2013
13:29
Archive

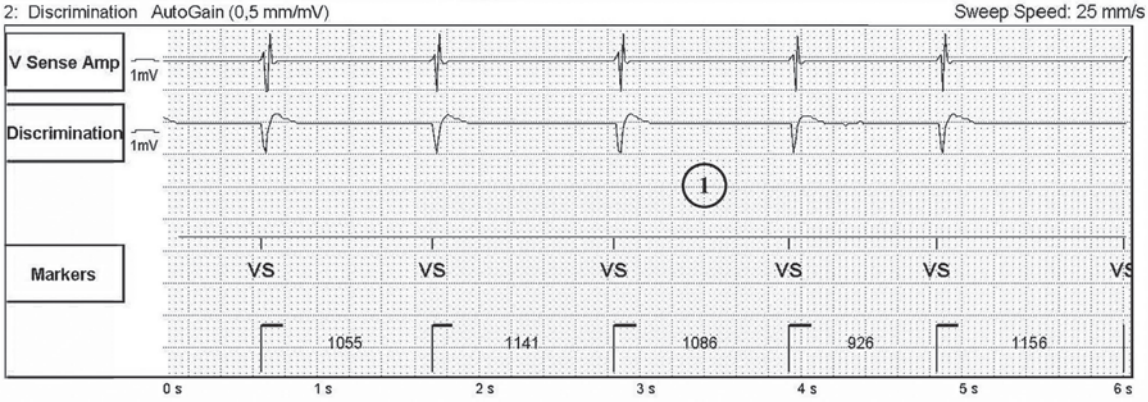
Episode: VF (230 bpm / 260 ms)

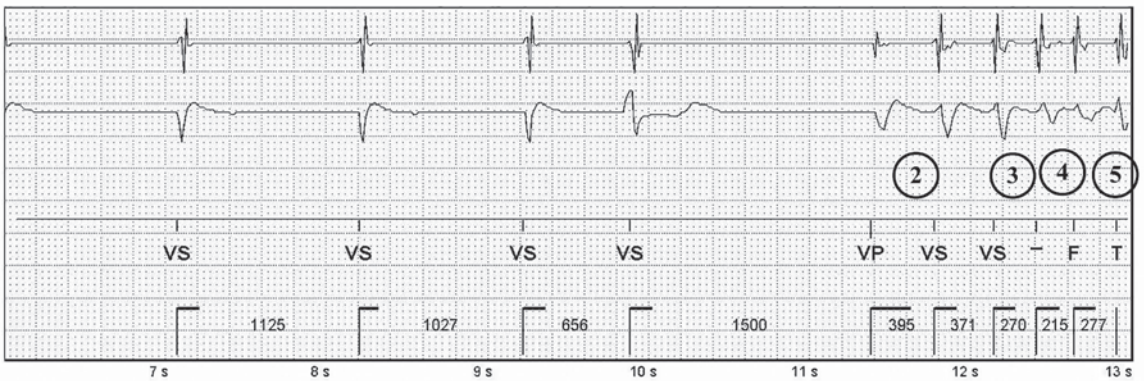
11 Mar 2013 18:18

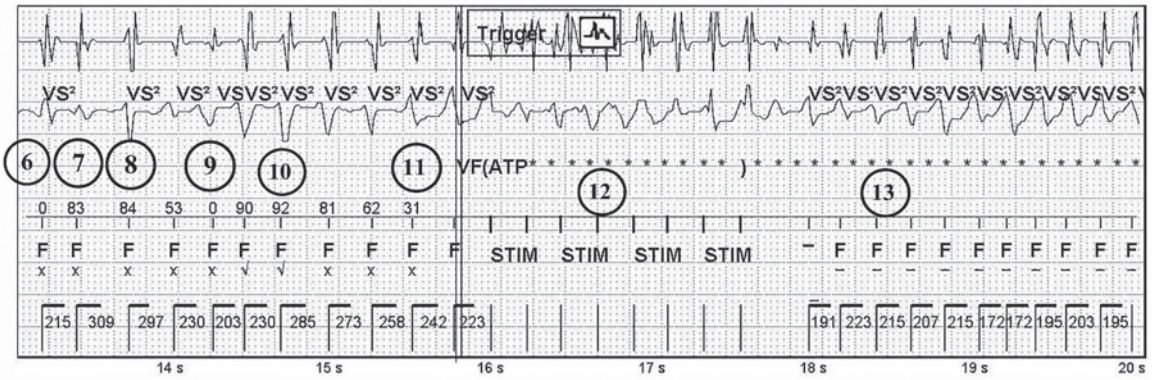
VT/VF Episode 2 of 3
Page 2 of 3

1: V Sense Amp AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (0,5 mm/mV)
3: Markers

Sweep Speed: 25 mm/s







VT/VF Episode 2 of 3 Page 2 of 3
13 Aug 2013 13:29

ST. JUDE MEDICAL

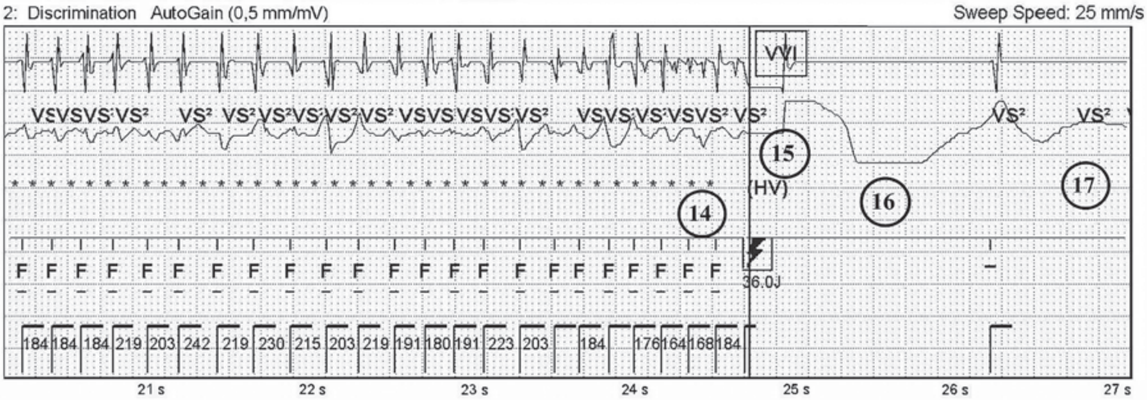
13 Aug 2013
13:29
Archive

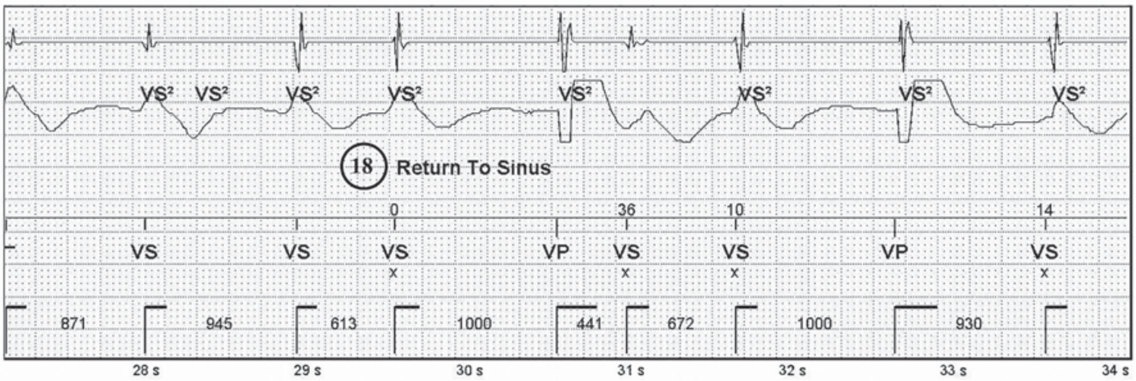
Episode: VF (230 bpm / 260 ms) (Continued)

VT/VF Episode 2 of 3
Page 3 of 3

11 Mar 2013 18:18

1: V Sense Amp AutoGain (0,4 mm/mV) 3: Markers
2: Discrimination AutoGain (0,5 mm/mV) Sweep Speed: 25 mm/s





VT/VF Episode 2 of 3 Page 3 of 3
13 Aug 2013 13:29

Tracing 2: SecureSense™ algorithm and lead dysfunction

Patient

This 52-year-old man received a Saint Jude Medical, single chamber, Fortify Assura™ VR defibrillator for a secondary prevention indication (aborted sudden death due to ischemic cardiomyopathy). A remote monitoring alert and a patient warning (vibration) were issued, prompting an early consultation after 13 episodes diagnosed by the device. The ventricular pacing threshold was stable, the sensitivity acceptable, and the pacing impedance slightly decreased. Two detection zones were programmed, including VF at 200 bpm (300 ms cycle length) and VT at 181 bpm (330 ms cycle length). The SecureSense™ algorithm was programmed ON (between the RV coil and the can).

Tracing 2A

Episode of noise on the ventricular lead

1: sinus rhythm; the beginning of the tracing shows the VS2 markers on the discrimination channel; from that cycle onward, the VS2 markers are interrupted, corresponding to a deactivation of the noise counter after 255 VS or VP cycles;
2: first short cycle (-) on the bipolar channel, indicative of oversensing on the bipolar channel (very low-amplitude signal preceding the QRS);
3: second short cycle (-) on the bipolar channel; onset of 350-ms warm-up before reactivation of the noise counter;
4: first F-classified cycles increasing the VF counter; persistence of oversensing on the bipolar channel and absence of detection on the discrimination channel;
5: accurate sensing of the QRS complexes on the discrimination channel;
6: increment in parallel of the VF and noise counters (short cycles are present on the bipolar channel and absent on the discrimination channel);
7: the VF counter is filled (12); the noise counter is ≥10, prompting the diagnosis of noise on the RV lead and inhibiting the therapies;
8: return to sinus rhythm diagnosed after 3 consecutive VS cycles (absence of oversensing);

Tracing 2B

Episode of non-sustained ventricular oversensing (same patient)

9: sinus rhythm; the presence of VS2 markers on the discrimination channel indicates that the noise counter was activated and that it was increased before the beginning of the tracing;
10: oversensing with short cycles on the bipolar channel (-) increasing the noise counter (absence of oversensing on the discrimination channel);
11: the noise counter is at 10 (10 short cycles on the bipolar channel) while the VF or VT counters are not filled; diagnosis of non-sustained ventricular oversensing (SNS);

Comments

This tracing illustrates characteristic aspects of the SecureSense™ algorithm function during an episode of lead dysfunction:
1) the VS2 markers are present from the very beginning of the tracing, indicating a prior activation of the noise counter. Once activated, the noise counter is not immediately deactivated, despite the cessation of the arrhythmia or oversensing that caused its activation, since 255 VS or VP cycles are needed on the bipolar channel. Therefore, the noise counter remains active for >4 minutes, for a rate of 60 bpm. This latency illustrates oversensing issues, even when they are highly sporadic and when the arrhythmia counters do not have the time to fill up, representing a major advantage of this algorithm. The repetitive occurrence of sequences, which include, for example, a single oversensed cycle (VS,VS,VS,VS, -) gradually increases the noise counter (recording of an episode of non-sustained noise in the memories), which increases considerably the ability to diagnose oversensing issues compared with standard devices, which require either episodes of non-sustained ventricular arrhythmias with a

minimum number of consecutive cycles, or sustained episodes, to trigger a recording.
2) in the initial phase of lead dysfunction, oversensing may be limited to the bipolar channel and be absent on the discrimination channel. This divergence is the base of the algorithm function. The noise counter increases with each short cycle on the bipolar channel, and the absence of short cycles on the discrimination channel explains why it is not reset to 0. The inappropriate therapies are, therefore, inhibited representing a major advantage from the perspective of quality of life and prognosis.
3) a therapy inhibited by the SecureSenseTM triggers a patient warning and a remote monitoring alert, shortening the delay between the diagnosis of dysfunction by the device and the onset of medical management, an essential element behind the prevention of inappropriate therapies. It seems nevertheless evident that, while the SecureSenseTM algorithm enables a rapid diagnosis of lead dysfunction and lowers the risk of inappropriate therapies, the dysfunctional lead must be rapidly replaced. It is not advised to rely on the algorithm only to avoid the delivery of inappropriate therapies over the long term, especially since the lead dysfunction tends to increase over time.

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9 Jan 2014
9:31
Archive

Episode: VF, V Lead Noise (250 bpm / 240 ms)

VT/VF Episode 3 of 47
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29 Jul 2013 7:45

Duration	00:08 (M:S)	**Alerts**	**SecureSense™ is On, and it inhibited therapy due to V lead noise**
Detection Criteria	200 bpm	⚠	

Therapy	**Results**
All therapies were inhibited.	

Diagnosis Summary

	Diagnosis
	V Lead Noise
Time to Diagnosis	5,50 sec
Rate (CL)	250 bpm (240 ms)

DeFT Response™ Settings (Shock Waveform)			**1st Phase**	**2nd Phase**
Waveform	Biphasic	VF Shocks (Defib)	65 %	65 %
Waveform Mode	Tilt	VT Shocks (CVRT)	Same as Defib	Same as Defib
Shock Configuration	RV to Can			
RV Polarity	Anode(+)			
Defib Max Sensitivity	0.5 mV			

ST. JUDE MEDICAL

9 Jan 2014
9:31
Archive

Episode: VF, V Lead Noise (250 bpm / 240 ms)

VT/VF Episode 3 of 47
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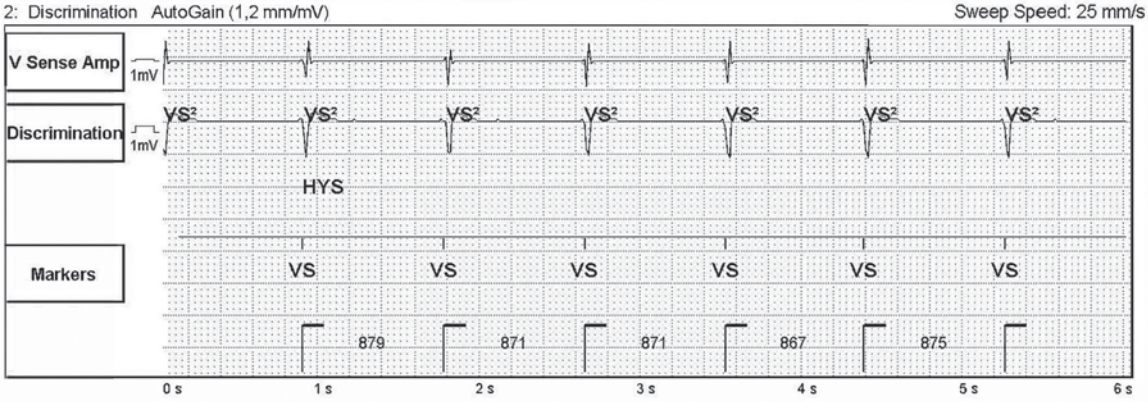
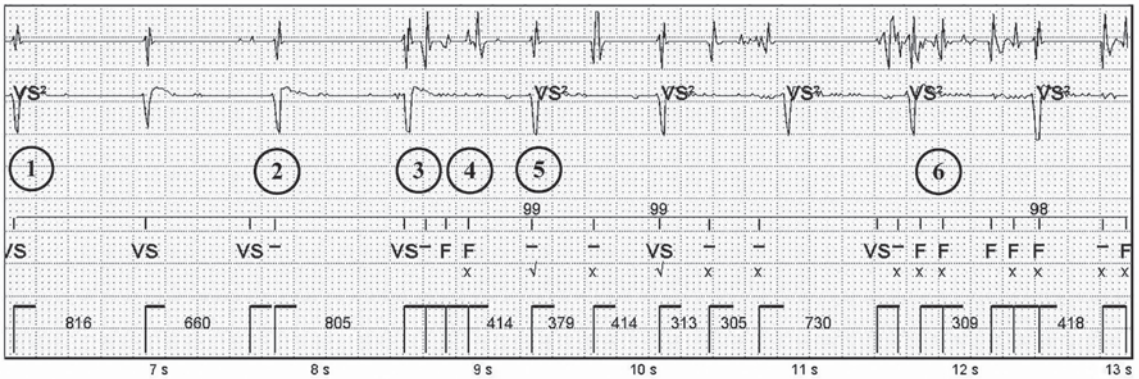
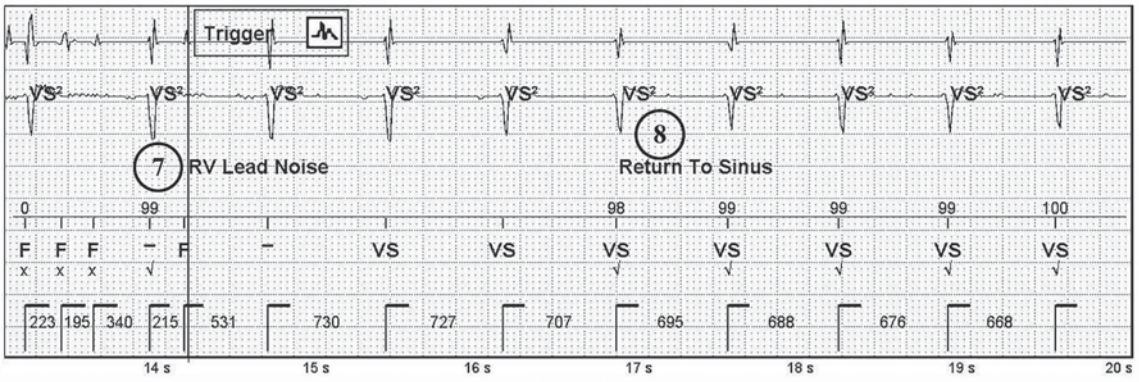
29 Jul 2013 7:45

1: V Sense Amp AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (1,2 mm/mV)
3: Markers

Sweep Speed: 25 mm/s







ST. JUDE MEDICAL

9 Jan 2014
9:31
Archive

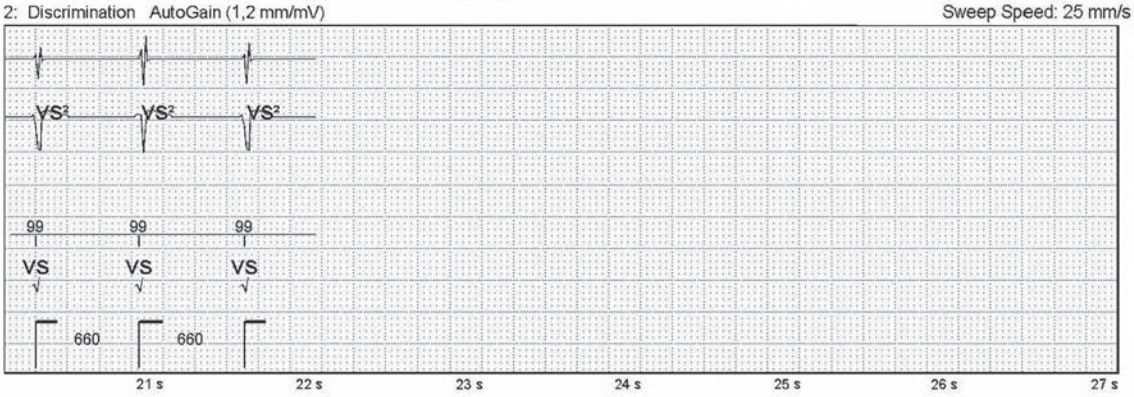
Episode: VF, V Lead Noise (250 bpm / 240 ms)

VT/VF Episode 3 of 47
Page 3 of 3

29 Jul 2013 7:45

1: V Sense Amp AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (1,2 mm/mV)
3: Markers

Sweep Speed: 25 mm/s



ST. JUDE MEDICAL

9 Jan 2014
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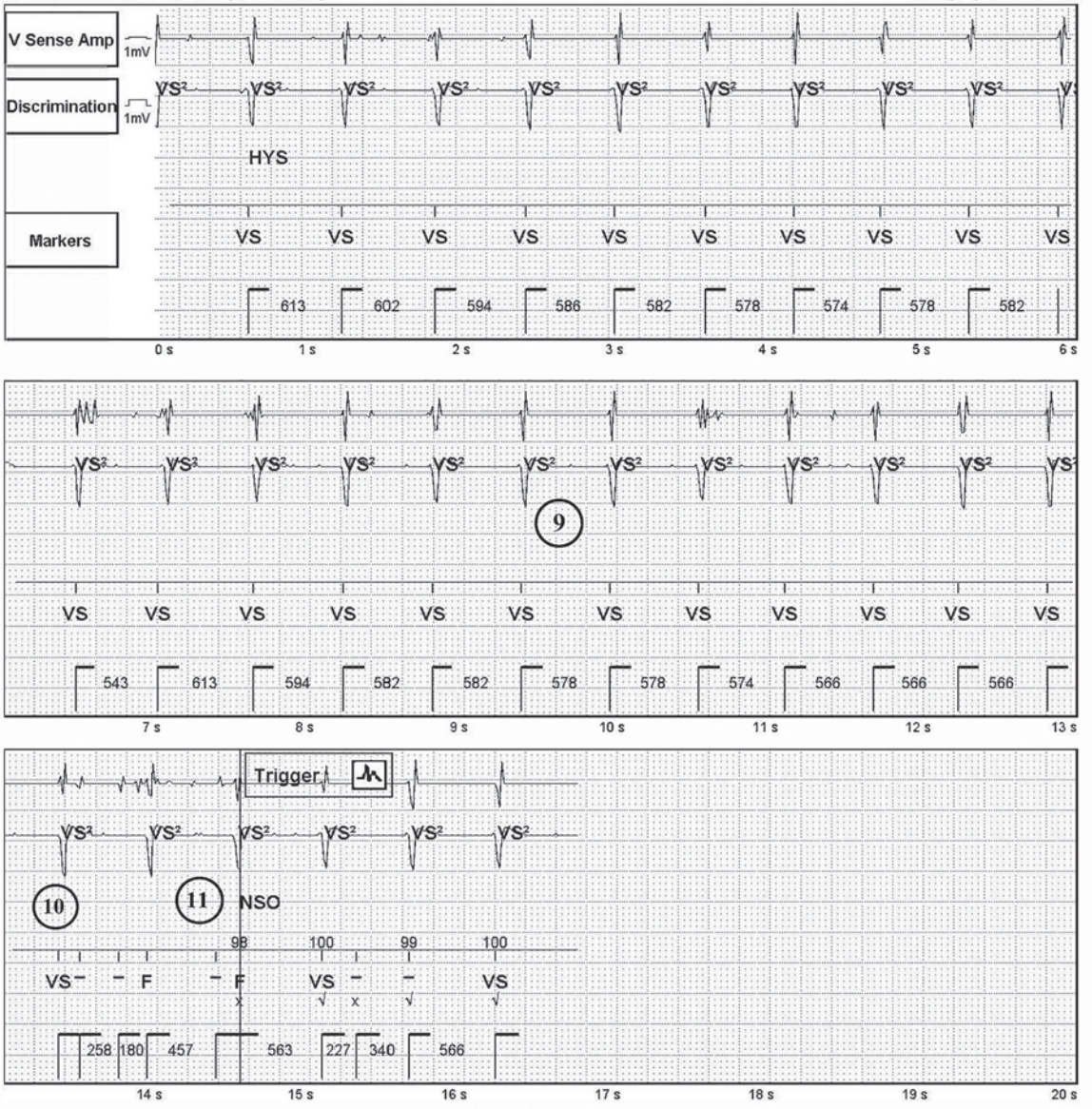
Archive

Episode: Non-sustained V Oversensing

Other Episode 57 of 57
Page 1 of 1

9 Jan 2014 7:58
Mode VVI

1: V Sense Amp AutoGain (0,4 mm/mV)
2: Discrimination AutoGain (1,1 mm/mV)
3: Markers
Sweep Speed: 25 mm/s



Other Episode 57 of 57 Page 1 of 1
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Tracing 3: SecureSense™ algorithm and T waves oversensing during spontaneous ventricular rhythm

Patient

This 69-year-old man presenting with an ischemic cardiomyopathy received a Saint Jude Medical Ellipse™ DR dual chamber defibrillator for a primary prevention indication. Episodes of non-sustained ventricular oversensing were recorded in the memories. Two zones of detection were programmed, including VF at 222 bpm (270 ms cycle length) and VT at 171 bpm (350 ms cycle length). The SecureSense™ algorithm was programmed ON (between the RV coil and the can).

Tracing

1: sinus rhythm; the presence of VS2 markers on the discrimination channel, in the beginning of tracing, indicates that the noise counter is activated;
2: T-wave oversensing (post R wave) limited to the bipolar channel (no VS2 marker in the discrimination channel);
3: short cycles on the bipolar channel (-) corresponding to the next QRS complex (short TR interval); absence of short cycles on the discrimination channel; the noise counter increases by +1;
4: further T wave oversensing on the bipolar channel;
5: short cycles are present on the bipolar though not on the discrimination channel;
6: T wave oversensing on the bipolar channel with 2 markers for each cycle, in contrast with a single VS² marker for each cycle on the discrimination channel;
7: the noise counter is at 10 whereas the VF or VT counter is not filled; diagnosis of non-sustained ventricular oversensing (SNS);

Comments

T-wave oversensing during spontaneous ventricular rhythm remains a serious problem of management of ICD recipients. It may be the cause of inappropriate therapies, particularly during exercise, when the RT and TR intervals are consistent with the VF zone. T wave oversensing is associated with a typical aspect of alternans between 2 morphologically different signals: a high frequency signal (R wave) and a low frequency signal (T wave). With each cardiac cycle, the device counts an R and a T wave, this second signal doubling of the heart rate.
T wave oversensing after a spontaneous ventricular event occurs preferentially, as in this example, in presence of low-amplitude R waves. Both the sensitivity and the gain are automatically adjusted to the amplitude of the sensed R wave. When the R wave amplitude is low, the device reaches rapidly high sensitivity levels, which facilitates oversensing of the T wave. The Saint Jude Medical devices allow the programming of specific settings to conceal and prevent the detection of T waves, including ventricular sensitivity, threshold start, decay delay and ventricular filters. The reprogramming choices are limited, however, when the main problem is a low-amplitude R wave.
The SecureSense™ algorithm was initially conceived to prevent the delivery of inappropriate therapies due to lead rupture. It also represents a major progress in the management of T wave oversensing. To trigger the delivery of inappropriate therapy, oversensing must occur nearly simultaneously on the bipolar and on the discrimination channels. The presence of the very precise conditions causing T wave oversensing (low-amplitude R wave, low R/T ratio, unfiltered T wave) at the same time on both channels is improbable. In this example, the T wave is oversensed on the bipolar channel only when the preceding R wave amplitude is low. On the other hand, the amplitude of the R wave on the discrimination channel is visibly much taller, explaining the absence of oversensing on this channel. Therefore, the noise counter increases with each short cycle on the bipolar channel without being reset to 0. Even if the VF counter had been filled, the therapies had been inhibited, since the count on the noise counter exceeded 10.
This tracing also shows that this algorithm allows a rapid diagnosis, including when oversensing is intermittent. Without the programming of the SecureSense™ algorithm, oversensing observed

on this tracing would have remained unnoticed. In practice, programming of this algorithm lowers considerably the delivery of inappropriate shocks due to T wave oversensing.

ST. JUDE MEDICAL

4 Jun 2015
14:05
Archive

Episode: Non-sustained V Oversensing

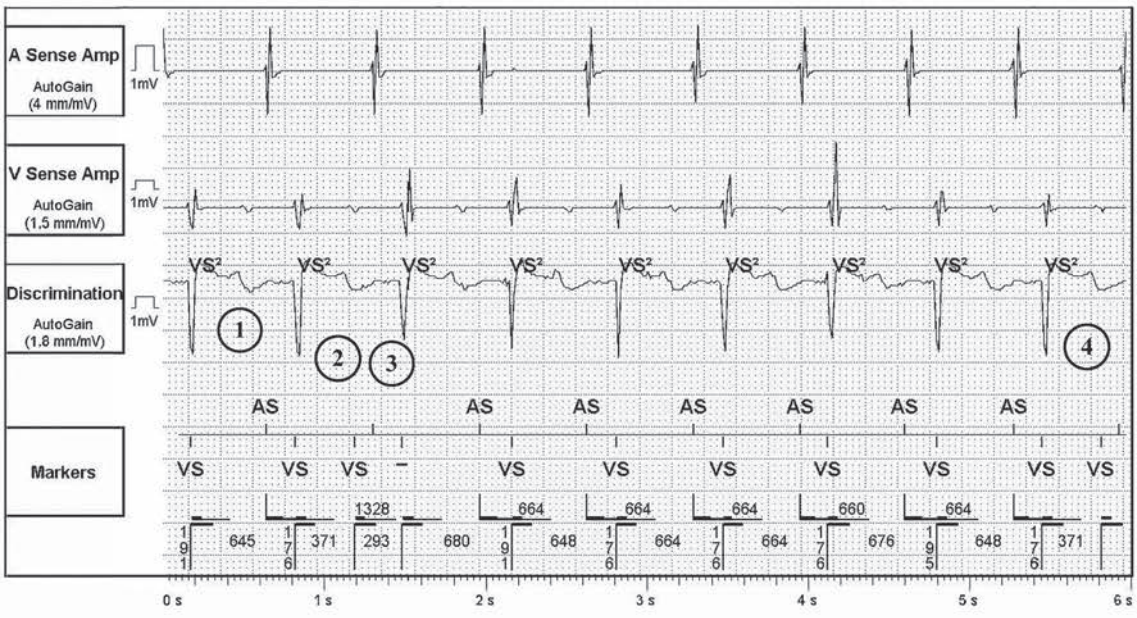
Other Episode 36 of 46
Page 1 of 2

19 Feb 2015 9:36

Mode DDD

1: A Sense Amp AutoGain (4,0 mm/mV)
2: V Sense Amp AutoGain (1,5 mm/mV)
3: Discrimination AutoGain (1,8 mm/mV)
4: Markers

Sweep Speed: 25 mm/s



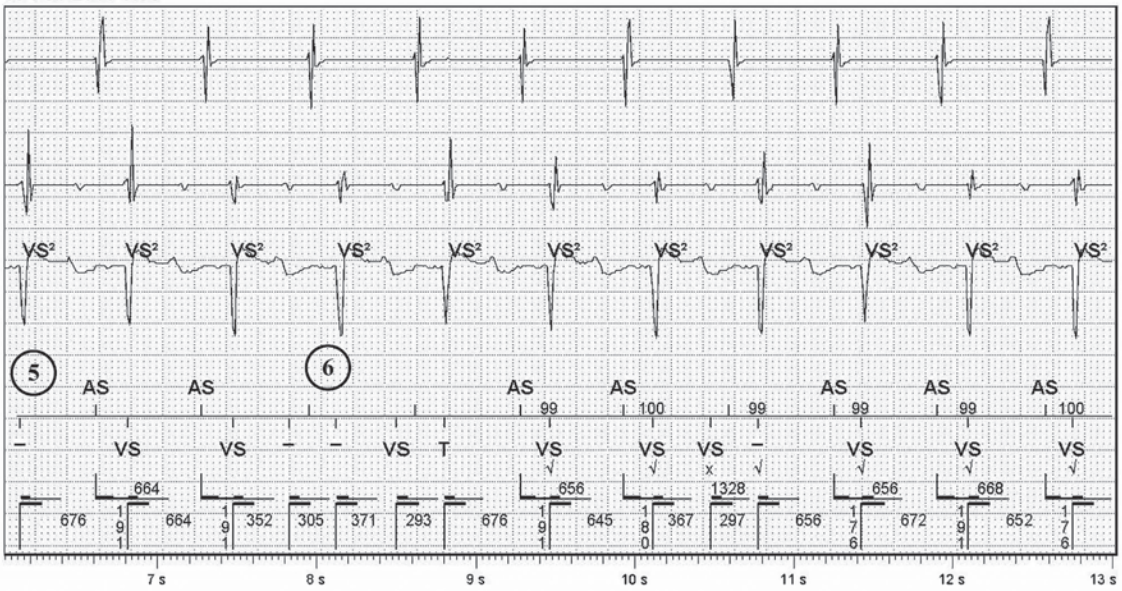
ST. JUDE MEDICAL

4 Jun 2015
14:05
Archive

Episode: Non-sustained V Oversensing (Continued)

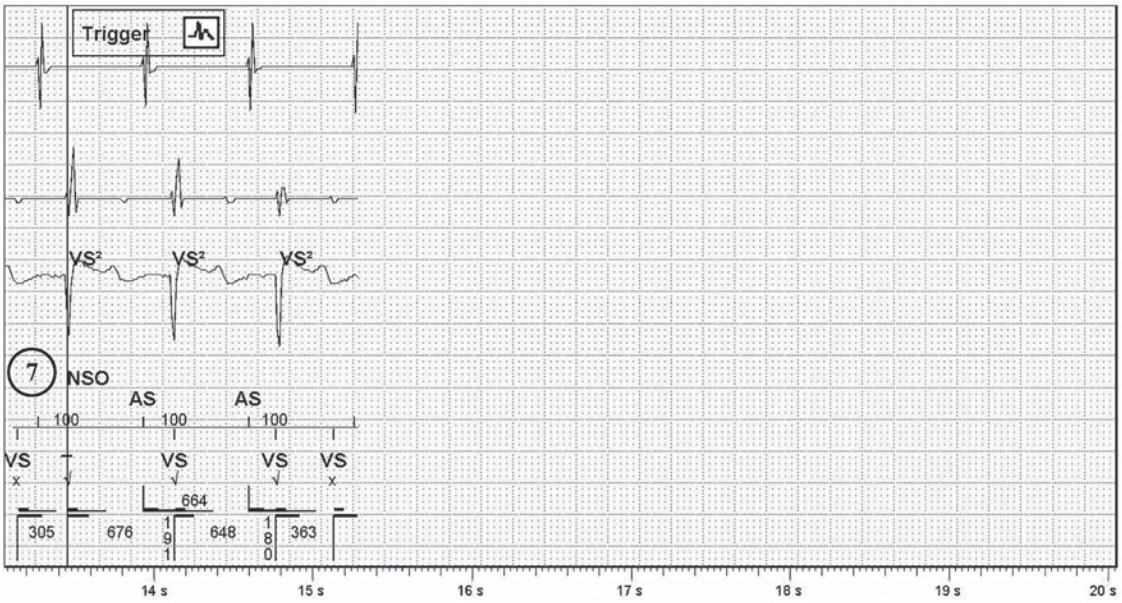
Other Episode 36 of 46
Page 2 of 2

19 Feb 2015 9:36



1: A Sense Amp AutoGain (4,0 mm/mV)
2: V Sense Amp AutoGain (1,5 mm/mV)
3: Discrimination AutoGain (1,8 mm/mV)
4: Markers

Sweep Speed: 25 mm/s



Tracing 4: SecureSense™ algorithm and T wave oversensing during ventricular pacing

Patient

This 67-year-old man presenting with dilated cardiomyopathy and left bundle branch block received a Unify Assura™ triple chamber ICD. Episodes of non-sustained RV oversensing were stored in the device memories.

Tracing

1: VS2 markers present on the discrimination channel indicate that the noise counter was activated and previously incremented;
2: atrial sensing and biventricular stimulation (AS-BV); post stimulation oversensing of the T wave is present on the bipolar channel and not on the discrimination channel;
3: further post stimulation T wave oversensing on the bipolar channel; short cycles increment the noise counter; the next ventricular cycle is spontaneous (VS), as ventricular stimulation after the atrial event was not possible without exceeding the maximum tracking rate; the percentage of biventricular stimulation decreases;
4: the noise counter is at 10 (10 short cycles on the bipolar channel; some cycles are not visible on this tracing) though the VF or VT counter is not filled; non-sustained ventricular oversensing (SNS) was diagnosed;

Comments

This recipient of a cardiac resynchronization system responded imperfectly to treatment, with a percentage of stimulation limited to 70%. The episodes recorded revealed non-sustained RV oversensing, allowing the diagnosis of post-pacing T wave oversensing, explaining the intermittent loss of biventricular stimulation with alternans between stimulated and sensed ventricle. While the SecureSense™ algorithm diagnoses, it does not eliminate T wave oversensing and its stimulation consequences (inhibition of biventricular stimulation after sensing of the T wave). One of the advantages of the Saint Jude Medical devices is the ability of programming differently the post-ventricular sensing and post-ventricular pacing settings, which require different adjustments. The change in post-pacing sensitivity enabled the correction of oversensing and the recovery of nearly 100% biventricular stimulation, which is mandatory for an optimal response to cardiac resynchronization.

ST. JUDE MEDICAL

24 Oct 2013
10:07
Archive

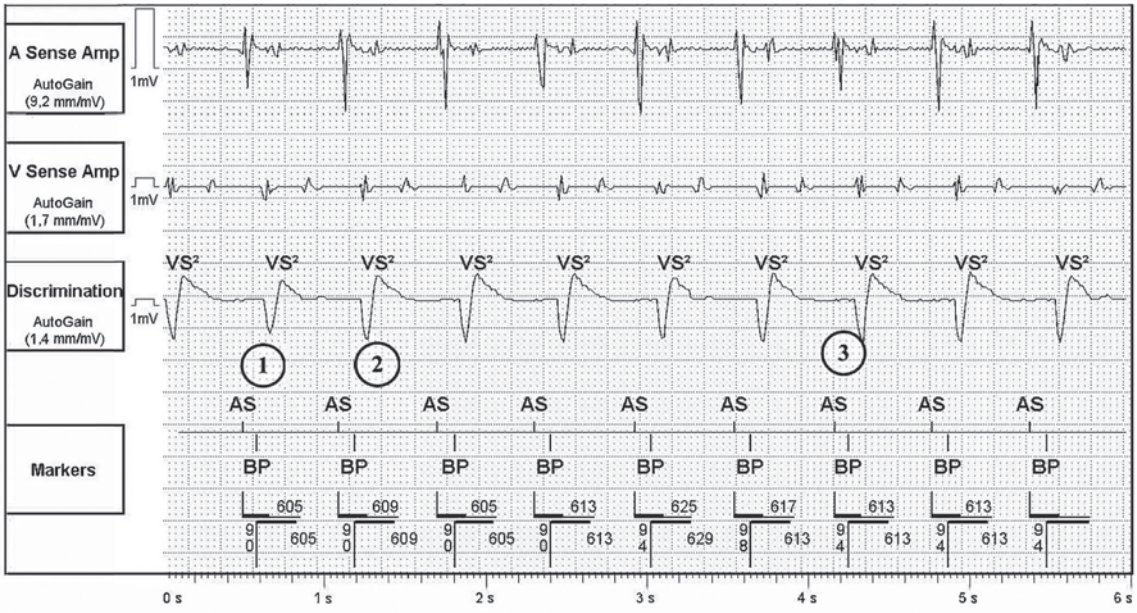
Episode: Non-sustained RV Oversensing

15 Oct 2013 19:25

Mode DDD

1: A Sense Amp AutoGain (9,2 mm/mV)
2: V Sense Amp AutoGain (1,7 mm/mV)
3: Discrimination AutoGain (1,4 mm/mV)
4: Markers

Sweep Speed: 25 mm/s



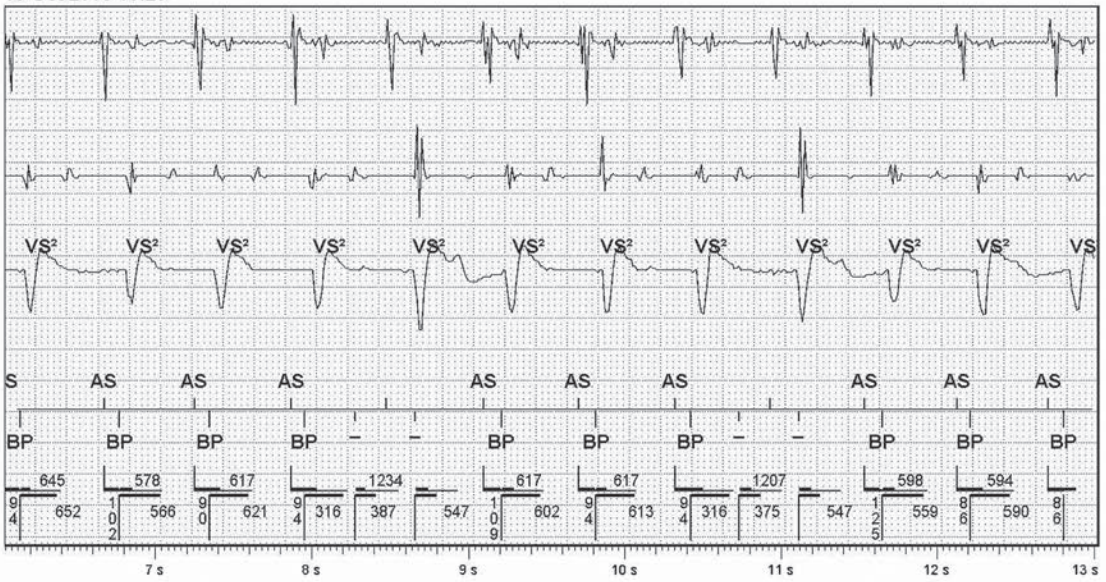
ST. JUDE MEDICAL

24 Oct 2013
10:07
Archive

Episode: Non-sustained RV Oversensing (Continued)

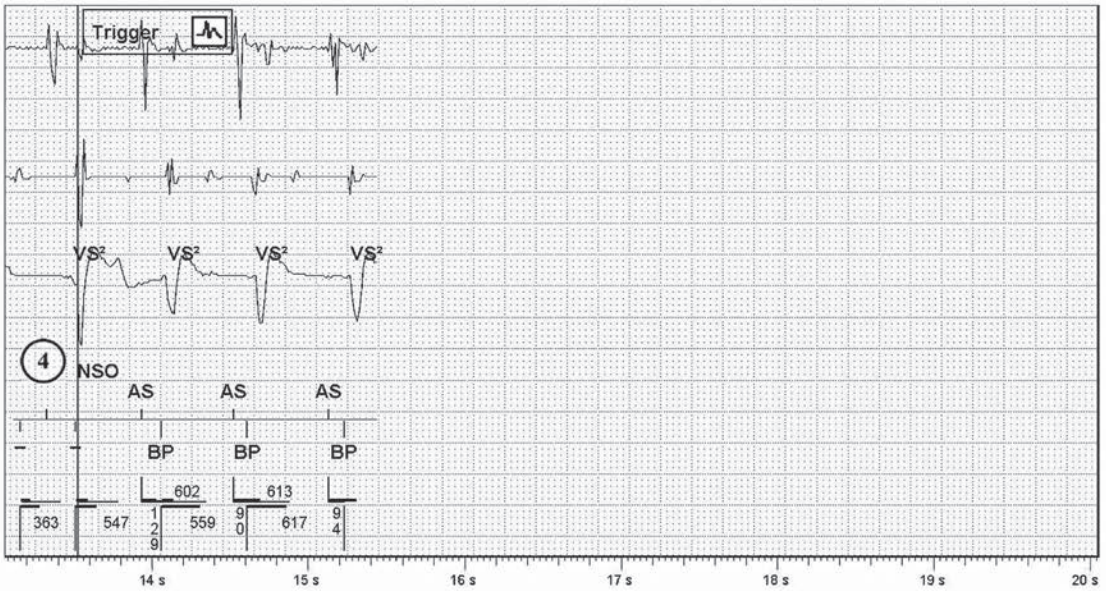
Other Episode 21 of 22
Page 2 of 2

15 Oct 2013 19:25



1: A Sense Amp AutoGain (9,2 mm/mV)
2: V Sense Amp AutoGain (1,7 mm/mV)
3: Discrimination AutoGain (1,4 mm/mV)
4: Markers

Sweep Speed: 25 mm/s



Tracing 5: SecureSense™ algorithm and P wave oversensing

Patient

This 65-year-old man received a Saint Jude Medical Ellipse™ VR defibrillator; an episode of noise on the ventricular lead was stored in the memories.

Tracing 5A

1: VS2 markers on the discrimination channel indicate that the noise counter was activated and had been previously incremented;
2: oversensing, on the bipolar channel, of a signal preceding the QRS complex, probably corresponding to P waves. Absence of oversensing on the discrimination channel. Alternans between a) non-classified cycle (the instantaneous interval is long though, on average, the interval is in a zone of tachycardia) and b) F-classified cycle (the instantaneous interval and the averaged interval are both in the tachycardia zone);
3: 2 VS-classified cycles (insufficient number of cycles to fill the counter of return to sinus rhythm);
4: another F-classified cycle; the VF counter continues to increase (it is at 9 with this cycle); in view of the absence of short cycles on the discrimination channel, the noise counter increases in parallel;
5: the VF counter is at 12 (full); the noise counter is ≥10; therefore, RV lead noise is diagnosed and the therapies are inhibited;

Patient

This 69-year-old man received a Saint Jude Medical Unify Assura™ triple chamber ICD for management of a dilated cardiomyopathy with non-specific bundle branch block; episode of VF diagnosed and stored in memory.

Tracing 5B

1: the VS2 markers present on the discrimination channel indicate that the noise counter had been activated and previously incremented; atrial sensing and biventricular stimulation; oversensing present on the discrimination channel and probably corresponding to P waves; no oversensing noted on the bipolar channel;
2: oversensing present on the bipolar channel as well as on the channel of atrial activity discrimination; stimulation is absent and spontaneous ventricular activity present (with a decrease in the percentage of biventricular stimulation) following that oversensing;
3: alternans of (-) and (F) cycles; gradual increment of the VF counter;
4: the VF counter is filled; the noise counter is frequently reset to 0 (alternans between long and short cycles on the discrimination channel; reset to 0 after 2 short cycles even when non-consecutive); since the noise counter is below 10, the therapies are not inhibited;
5: ATP during the charge (burst + charge of the capacitors);
6: persistence of oversensing on the discrimination channel and intermittent oversensing on the bipolar channel;
7: return to sinus rhythm diagnosed after 3 VS-classified cycles (intermittent oversensing);

Comments

Oversensing of atrial depolarization (P wave) by the RV lead is rare and is observed mainly in recipients of integrated bipolar leads. In patients in sinus rhythm, the RV lead senses both the atrial and ventricular depolarization since the PR interval is longer than the post-sensed ventricular blanking period. In patients presenting with complete AV block, P wave oversensing may inhibit ventricular pacing and cause asystole. Likewise, oversensing of atrial depolarization during flutter or atrial tachycardia may cause both inappropriate therapies and asystole if the patient is pacemaker-dependent.
Oversensing of the atrial signal occurs preferentially in 2 circumstances: 1) in case of RV lead

dislodgement at the AV junction (coincides with a fall in R wave amplitude), or 2) when an integrated bipolar lead is implanted near the tricuspid ring, with the distal coil straddling the valve (coinciding with a preserved R wave amplitude). This observation is more likely in patients whose cardiac chambers are small, such as children or patients presenting with hypertrophic cardiomyopathy.
Atrial oversensing may also occur under less common circumstances: 1) the RV lead has inadvertently been placed in the coronary sinus, 2) an insulation breakdown has occurred at the level of the atrial segment of the lead, causing oversensing of the atrial activity, 3) interaction between the atrial and the RV lead, with the leads in contact with each other and causing a signal at the time of atrial systole.
While, as discussed previously, the SecureSense™ algorithm can virtually eliminate the therapies triggered by T wave oversensing, it is less effective against P wave oversensing. If the discrimination channel is set between the coil and the can, oversensing on this channel is more likely (coil in the atrium if the lead is placed near the tricuspid valve) than on the bipolar channel (both electrodes in the ventricle). These 2 tracings illustrate 2 cases of figure:
- on the first tracing, oversensing is limited to the bipolar channel: the SecureSense™ algorithm prevents one or more inappropriate therapies, which would have been inevitable.
- on the second tracing, oversensing is incessant on the discrimination channel and intermittent on the bipolar channel. When the VF counter is filled, a therapy is inappropriately delivered.
By changing the discrimination channel to program the detection between the distal electrode and the pulse generator (tip to can), the risk of oversensing on this channel could be lowered, though would not eliminate oversensing on the bipolar channel. In both cases, repositioning of the high-voltage lead must be considered, while verifying during the implant that the distal coil is indeed completely contained in the RV chamber.

Episode: VF, V Lead Noise (226 bpm / 265 ms)

5 Nov 2015 13:40

Duration	00:54 (M:S)	**Alerts**	**SecureSense™ is On, and it inhibited therapy due to V lead noise**
Detection Criteria	222 bpm	⚠	

Therapy	**Results**
All therapies were inhibited.	

Diagnosis Summary

	Diagnosis
	V Lead Noise
Time to Diagnosis	32,00 sec
Rate (CL)	226 bpm (265 ms)

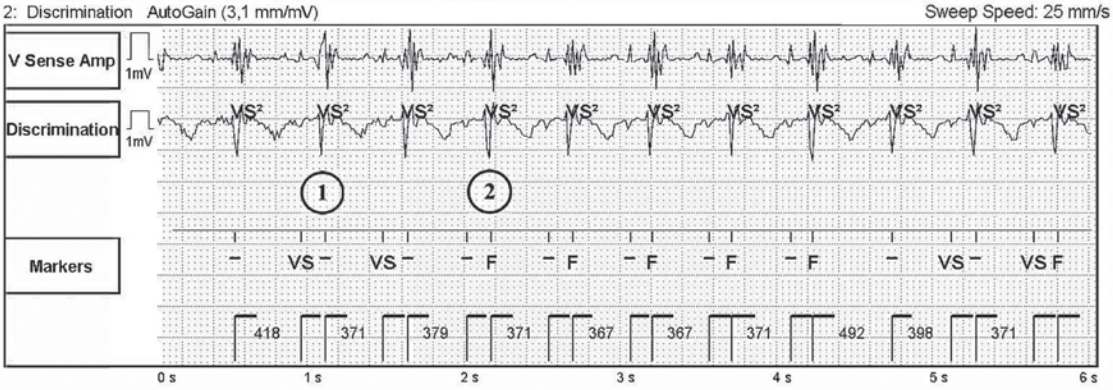
DeFT Response™ Settings (Shock Waveform)			**1st Phase**	**2nd Phase**
Waveform	Biphasic	VF Shocks (Defib)	65 %	65 %
Waveform Mode	Tilt	VT Shocks (CVRT)	Same as Defib	Same as Defib
Shock Configuration	RV to Can			
RV Polarity	Anode(+)			
Defib Max Sensitivity	0.5 mV			

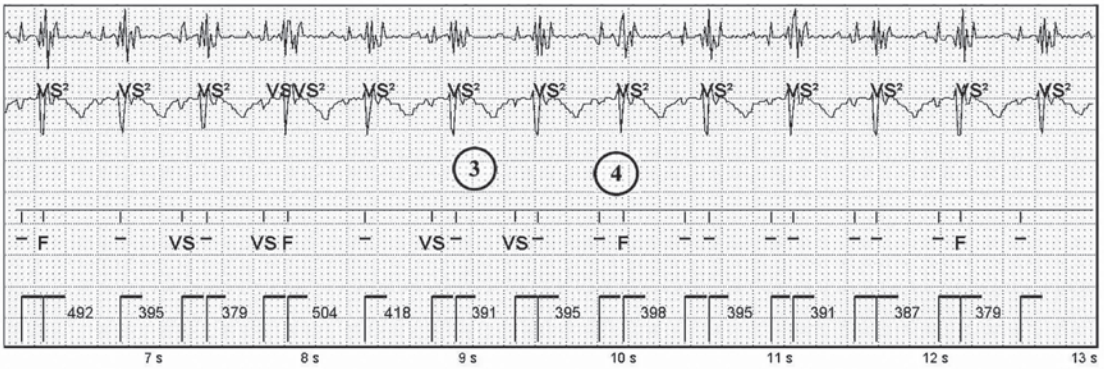
Episode: VF, V Lead Noise (226 bpm / 265 ms)

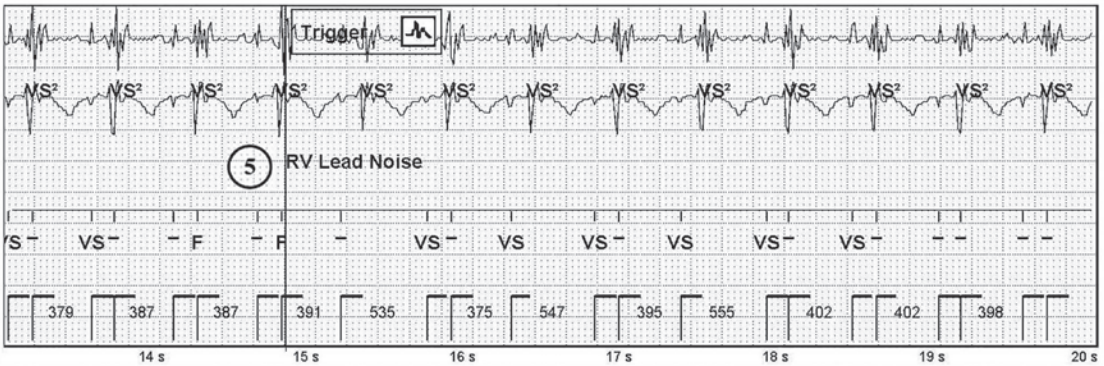
VT/VF Episode 21 of 47
Page 2 of 3

5 Nov 2015 13:40

1: V Sense Amp AutoGain (4,4 mm/mV) 3: Markers
2: Discrimination AutoGain (3,1 mm/mV)
Sweep Speed: 25 mm/s







VT/VF Episode 21 of 47 Page 2 of 3
6 Nov 2015 14:53

Episode: VF

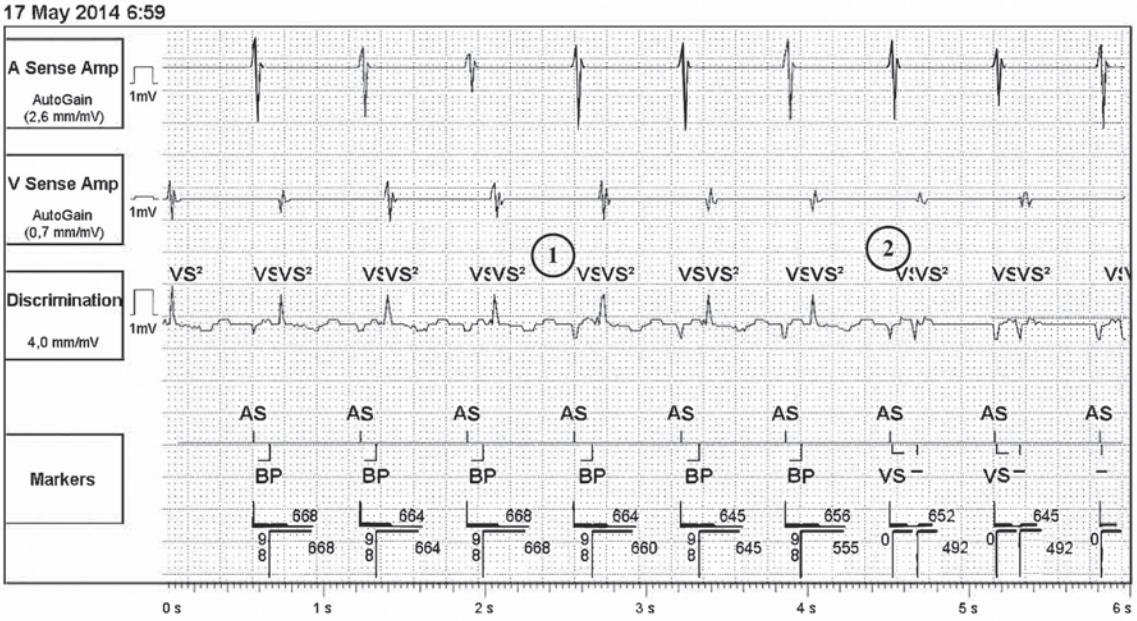
17 May 2014 6:59

Diagnostics and Parameters Unavailable

Episode: VF

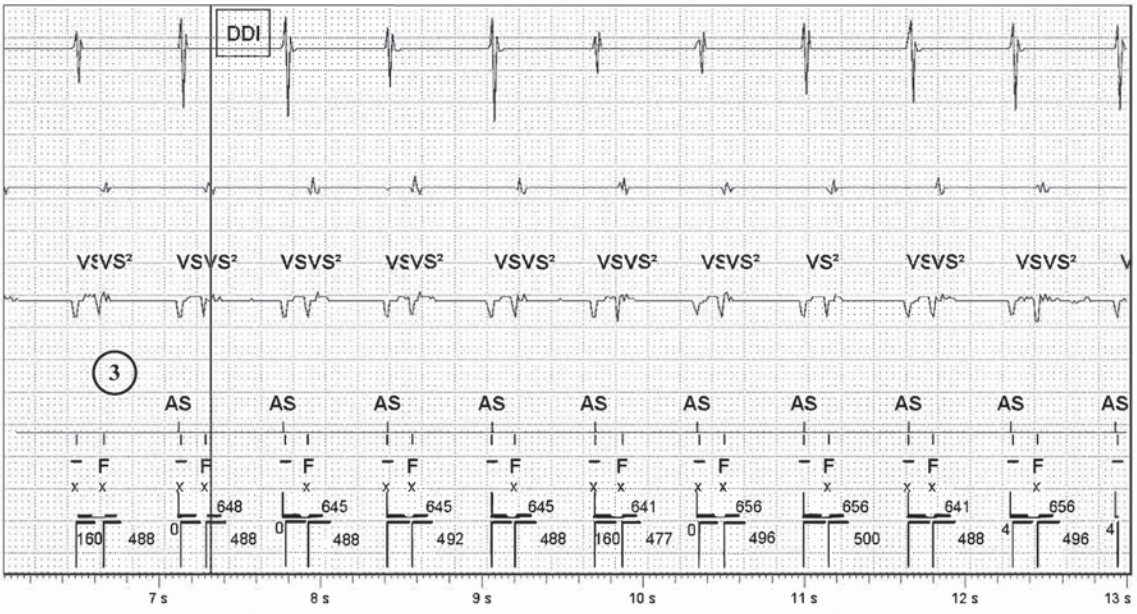
VT/VF Episode 2 of 31
Page 2 of 3

17 May 2014 6:59



1: A Sense Amp AutoGain (2,6 mm/mV)
2: V Sense Amp AutoGain (0,7 mm/mV)
3: Discrimination 4,0 mm/mV
4: Markers

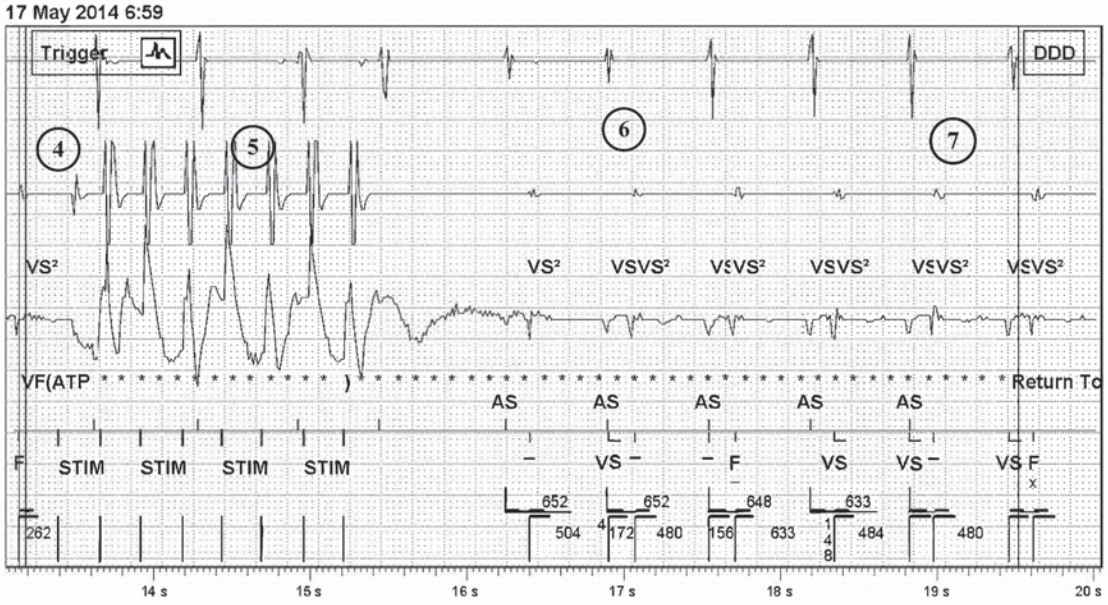
Sweep Speed: 25 mm/s



Episode: VF (Continued)

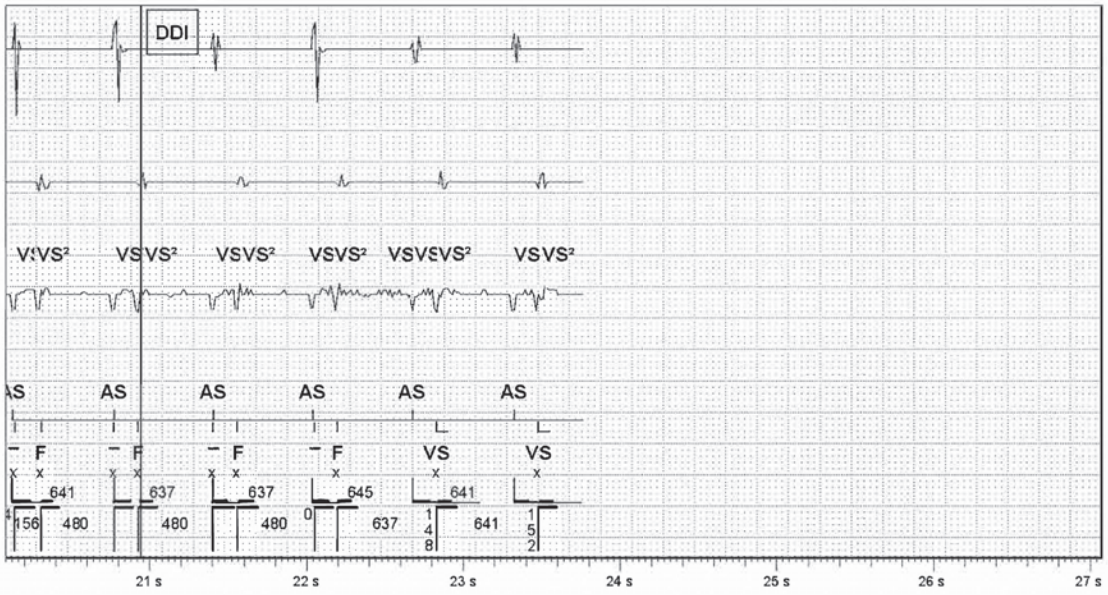
VT/VF Episode 2 of 31
Page 3 of 3

17 May 2014 6:59



1: A Sense Amp AutoGain (2,6 mm/mV)
2: V Sense Amp AutoGain (0,7 mm/mV)
3: Discrimination 4,0 mm/mV
4: Markers

Sweep Speed: 25 mm/s



Tracing 6: SecureSense™ algorithm and use of the electric scalpel

Patient

This 65-year-old man was implanted with a Saint Jude Medical Ellipse™ DR defibrillator. He received an electric shock during a surgical procedure.

Tracing

1: oversensing is visible on the atrial, ventricular and discrimination channels; the VF counter is filled; the noise counter has often been reset to 0 after the occurrence of short cycles on the discrimination channel; the capacitors begin to charge;
2: return to sinus rhythm diagnosed after 3 VS-classified cycles;
3: oversensing of large, fast and disorganized signals on both ventricular channels;
4: further oversensing;
5: the VF counter is filled (12); the noise counter is incessantly reset to 0; the therapies are not inhibited; the capacitors are charging;
6: short charge since the capacitors were already partially charged; at the end of the charge, new verification of the noise counter, which is <10; a 30-J shock is delivered;
7: interruption of oversensing and return to sinus rhythm diagnosed after 3 consecutive VS cycles;

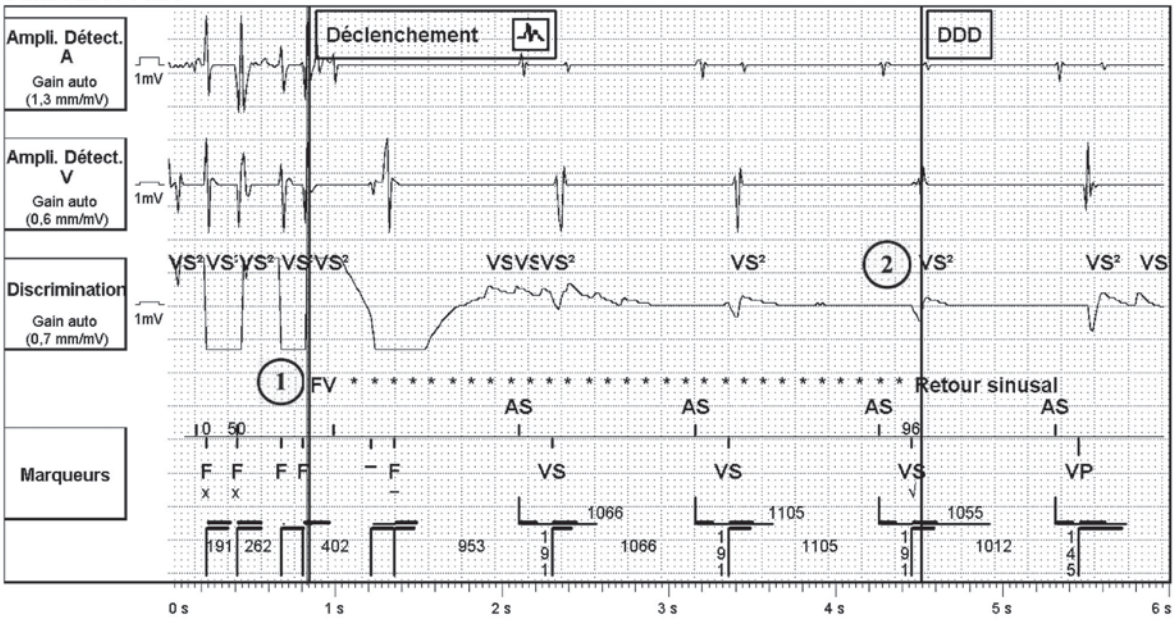
Comments

When a ICD recipient undergoes a surgical procedure, the surgeon must be advised to use the electric scalpel in the bipolar mode for brief periods, and to place the plate electrodes away from the pulse generator to keep the defibrillation system outside of the field created by the electric scalpel. The ICD must be temporarily deactivated to eliminate the risk of interference, and the patient must be monitored, with an external defibrillator available, if necessary. The device can be deactivated by applying a magnet over the can, or by deprogramming the device. The application of a magnet is usually preferred since, should a life-threatening arrhythmia develop, the ICD can be immediately reactivated by removing the magnet, which allows the immediate resumption of the detection of ventricular tachyarrhythmias. The absence or delay in the reactivation of therapies is not rare if the ICD was deprogrammed.
The aspect of the intracardiac EGM detected by the device is characteristic if its detection has not been deactivated, with presence of large, disorganized, and fast signals observed on the atrial, the bipolar and the discrimination channels. The coincidence with the surgical intervention confirms the diagnosis in most cases. The basic function of the SecureSense™ algorithm is the reason why the therapies are not inhibited for this type of oversensing, as the presence of short cycles on the discrimination channel reset the noise counter incessantly.

Episode: FV (279 min-1 / 215 ms)

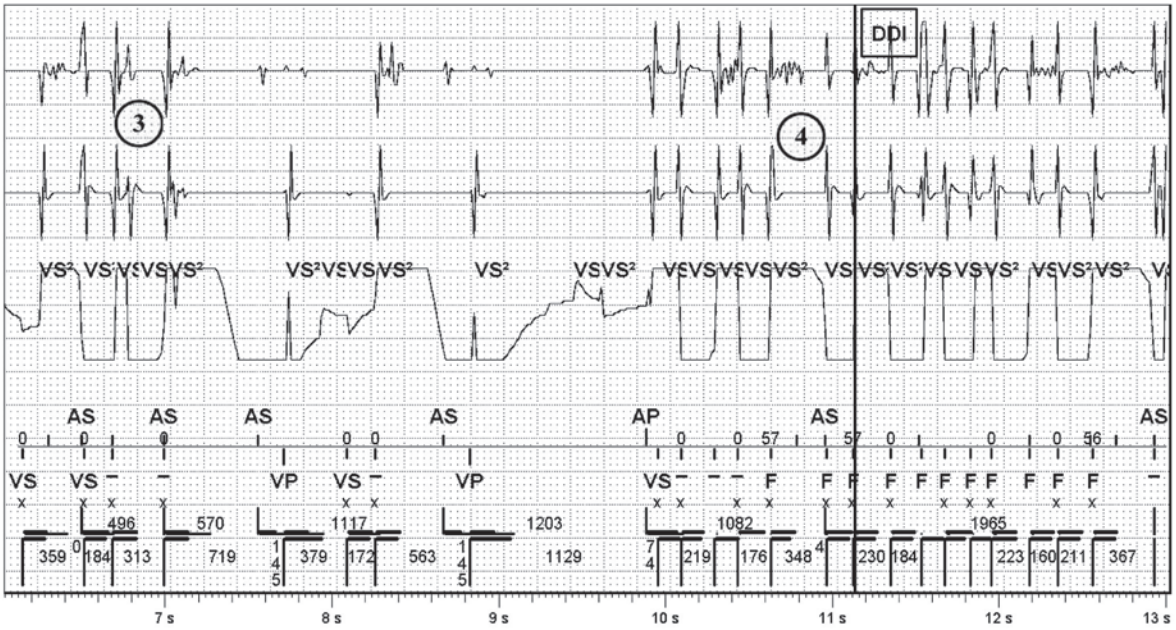
Épisode TV/FV 2 sur 6
Page 2 sur 3

1 mars 2014 14:14



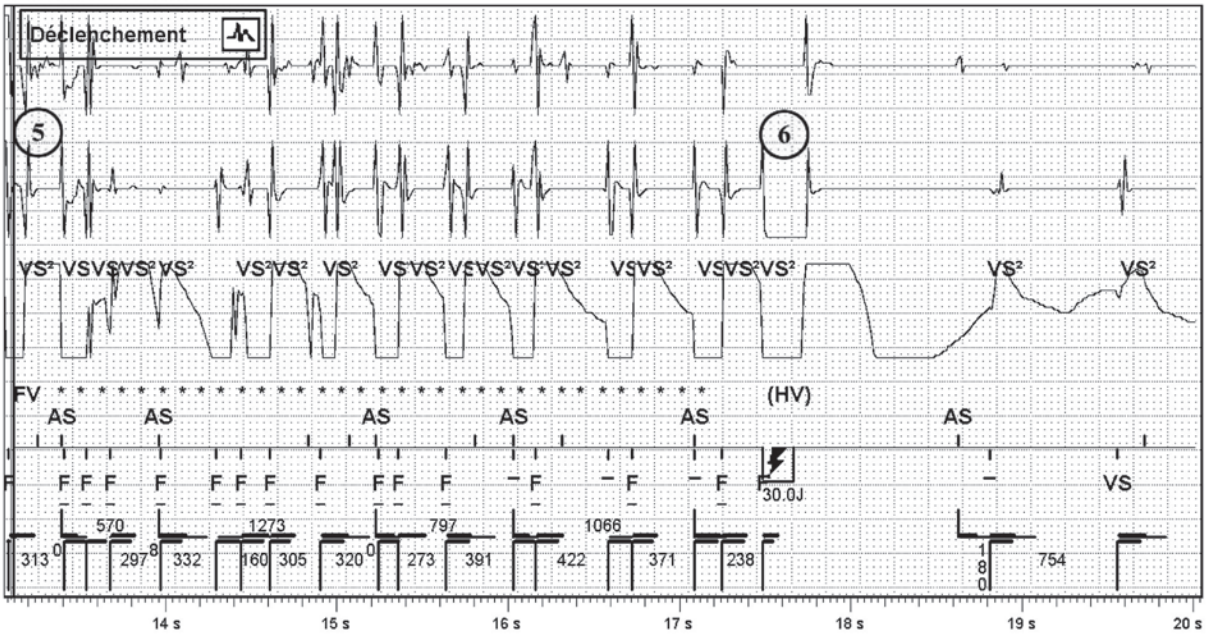
1: Ampli. Détect. A AutoGain (1,3 mm/mV)
2: Ampli. Détect. V AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (0,7 mm/mV)
4: Marqueurs

Vitesse de défilement : 25 mm/s



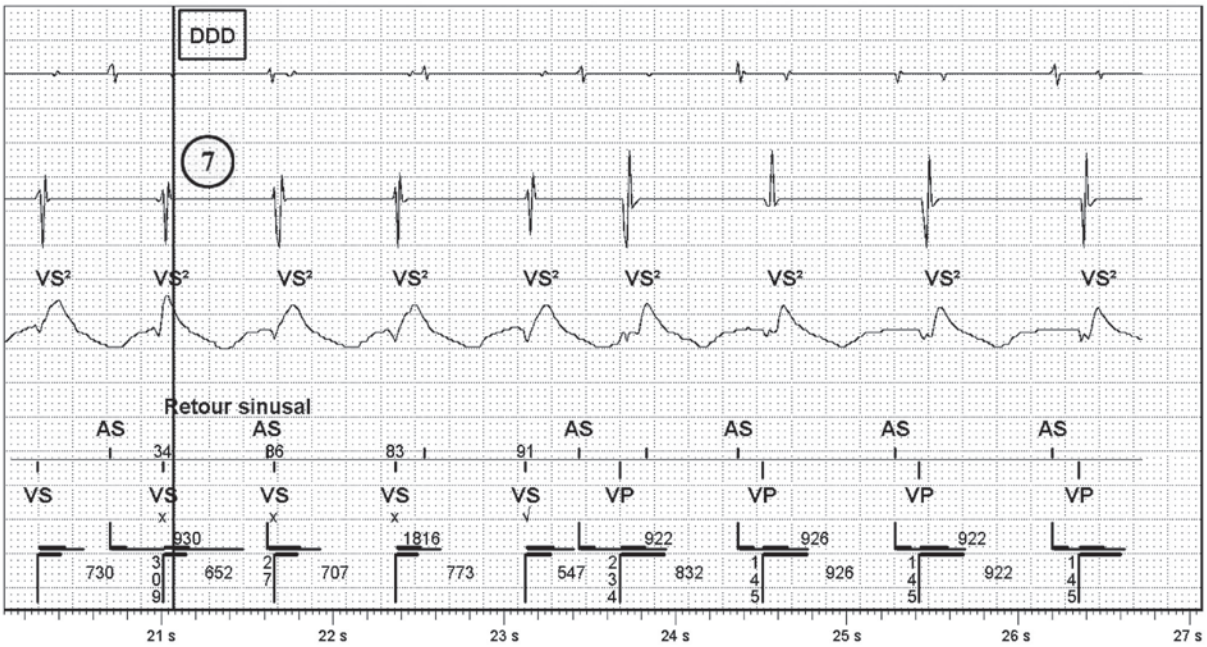
Episode: FV (279 min-1 / 215 ms) (Continued)

1 mars 2014 14:14



1: Ampli. Détect. A AutoGain (1,3 mm/mV)
2: Ampli. Détect. V AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (0,7 mm/mV)
4: Marqueurs

Vitesse de défilement : 25 mm/s



Tracing 7: SecureSense™ algorithm and loss of RV capture

Patient

This 76-year-old man received a Saint Jude Medical Ellipse™ DR defibrillator for the management of an ischemic cardiomyopathy with a long PR interval on the electrocardiogram. A non-sustained episode of noise on the ventricular lead was retrieved from the device memory.

Tracing

1: ventricular pacing and probable absence of capture (absence of ventricular depolarization on the discrimination channel); AV conduction with a prolonged PR interval and sensing of spontaneous ventricular activity on the bipolar channel (short cycles, -);
2: same sequence with a second short cycle; activation of the noise counter 350 ms after this second short cycle;
3: same sequence; the spontaneous QRS is sensed on the discrimination channel and marked VS2;
4: the noise counter is at 5, the VT or VF counter is not filled; diagnosis of non-sustained noise of ventricular lead (NSLN); the number 5, and the terms non-sustained noise ventricular lead, NSLN, date from old models. With the more recent models, a noise counter at 10 is needed to record an episode, and the terms applied are: diagnosis of non-sustained ventricular oversensing and SNS.

Comments

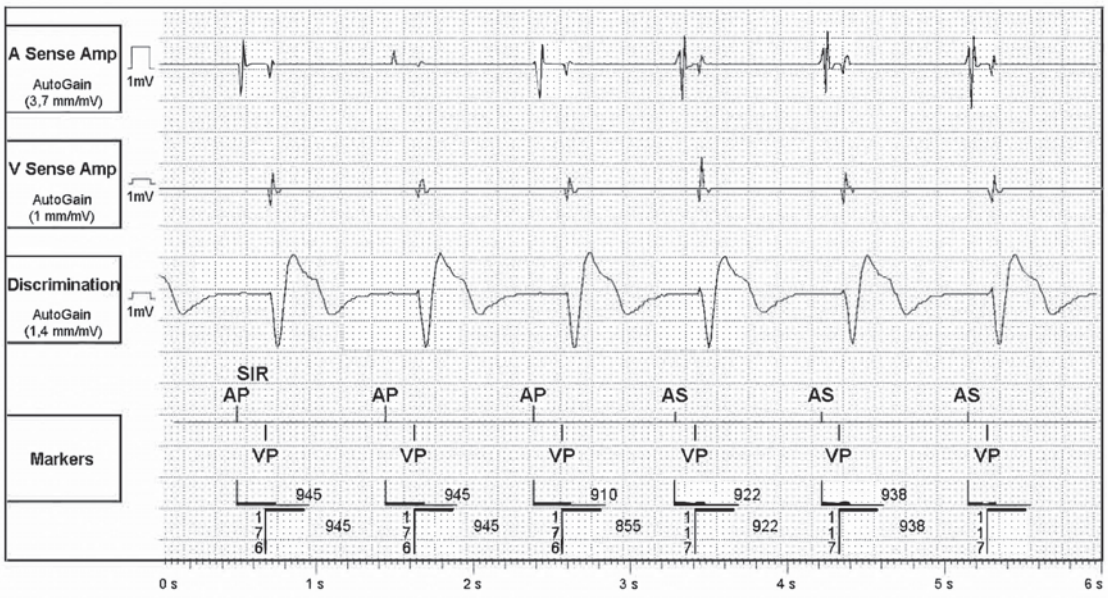
The activation of the SecureSense™ algorithm makes diagnoses that are sometimes unexpected as, in this case, the intermittent loss of RV capture. In this patient, the programmed amplitude of stimulation was too low, at the limit of threshold and without safety margin. With each loss of capture, a SecureSense™ alert was recorded. The delay between the ineffective ventricular stimulus and the sensing of spontaneous conducted activation was longer than the post-pacing ventricular blanking period and was expressed by the detection of a short cycle on the bipolar channel. Conversely, the spontaneous ventricular event was the only event sensed on the discrimination channel, explaining the absence of short cycle (no ventricular depolarization after the ventricular stimulus). An adapted programming of the stimulation amplitude solved the problem.

Episode: Non-sustained V Oversensing

10 Mar 2013 14:58
Mode n/a

1: A Sense Amp AutoGain (3,7 mm/mV)
2: V Sense Amp AutoGain (1,0 mm/mV)
3: Discrimination AutoGain (1,4 mm/mV)
4: Markers

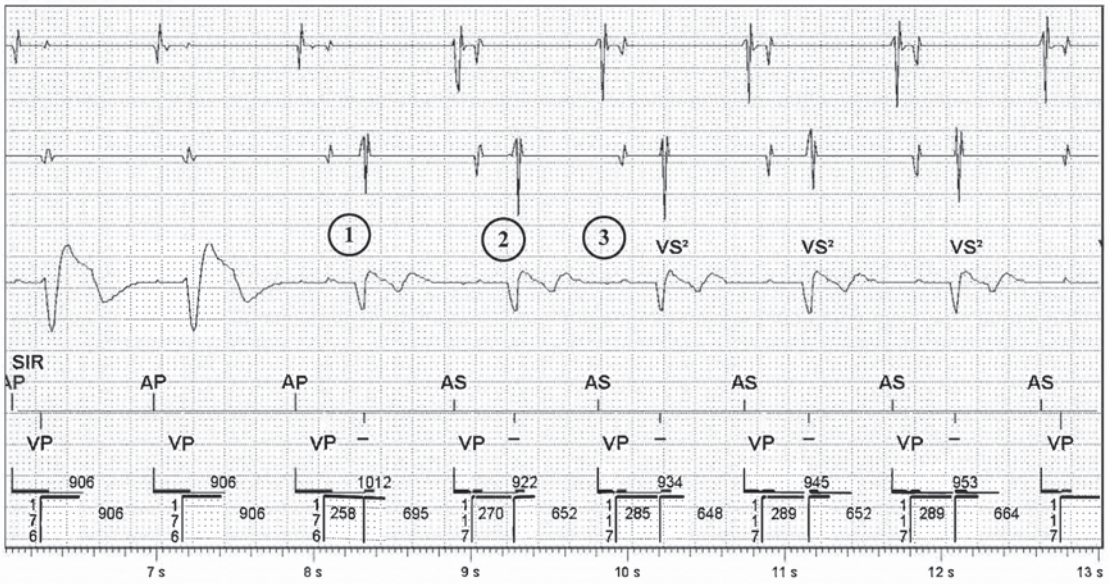
Sweep Speed: 25 mm/s



Episode: Non-sustained V Oversensing (Continued)

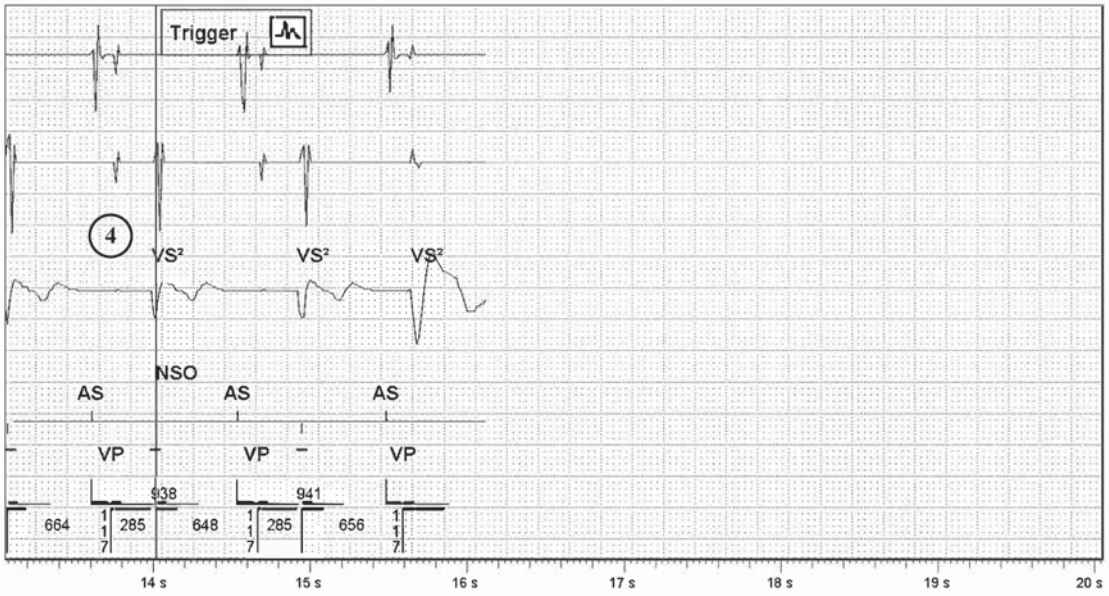
Other Episode 4 of 35
Page 2 of 2

10 Mar 2013 14:58



1: A Sense Amp AutoGain (3,7 mm/mV)
2: V Sense Amp AutoGain (1,0 mm/mV)
3: Discrimination AutoGain (1,4 mm/mV)
4: Markers

Sweep Speed: 25 mm/s



Tracing 8: SecureSense™ algorithm and timing difference between the 2 channels

Patient

This 35-year-old man received a Saint Jude Medical Ellipse™ DR dual chamber defibrillator for the management of an arrhythmogenic RV dysplasia with right bundle branch block and ventricular extrasystoles. Episodes of non-sustained ventricular oversensing were stored in the device memories.

Tracing

1: the presence of VS2 markers on the discrimination channel indicates that the noise counter was activated and previously incremented;

2: ventricular bigeminy accurately sensed on the bipolar and on the discrimination channel; premature ventricular contraction systematically classified (-), as the instantaneous cycle was classified as short in the bipolar channel, whereas the average of 4 cycles fits in the sinus zone (discordance between instantaneous and average intervals); the noise counter increases with each short cycle on the bipolar channel; the tracing does not show the interval between the 2 cycles classified VS2 (between the sinus QRS complex and the PVC). The QRS complex seems to be detected first on the discrimination channel, which is coherent in view of the right bundle branch block (delayed sensing on the bipolar channel); in contrast, the PVC originating from the right ventricle (arrhythmogenic RV dysplasia) is sensed first on the bipolar channel (signal less prominent on the discrimination channel). The interval between these 2 signals is, therefore, shorter on the bipolar than on the discrimination channel;

3: the noise counter is at 10 whereas the VF or VT counter is not filled. Non-sustained ventricular oversensing (SNS) was diagnosed.

Comments

This unusual tracing may be observed when the SecureSense™ algorithm is programmed, with different sensing circuits on the 2 channels. In presence of premature ventricular contractions, the noise counter should be reset to 0 each time 2 short cycles have been detected on the discrimination channel. Some sensing delay of the signals may be present, however, between the 2 channels, which may cause a difference of classification, since a cycle may be considered short on the bipolar channel (increment of the noise counter), however long on the discrimination channel (no resetting to 0 of the counter). In this patient, the slower zone of tachycardia was programmed at 420 ms. A bigeminy and a coupling of the premature ventricular contraction were close to that slow zone limit (between 390 and 430 ms) with a (-) marker corresponding to a short cycle when the instantaneous interval was shorter than 420 ms. The limit defining a short cycle on the discrimination channel is 450 ms (420 + 30). The interpretation of the algorithm function is complicated by the absence of indication of instantaneous intervals on the discrimination channel and by presence of a single VS2 marker, which does not allow the differentiation of short from long cycles. The sinus QRS complex is sensed first on the discrimination channel, with a prominent delay on the bipolar channel due to the right bundle branch block (delayed activation of the right ventricle, which contains the lead). Conversely, the premature ventricular contractions originate from the right ventricle and are sensed early on the bipolar channel, and later, on the discrimination channel, with also a difference of a few dozens of ms. Ultimately, the difference in the timing of the sensing of these 2 signals explains that the cycles are classified as short (<420 ms) on the bipolar channel and long (>450 ms) on the discrimination channel leading to the recording of an episode classified false positively as oversensing by the device.

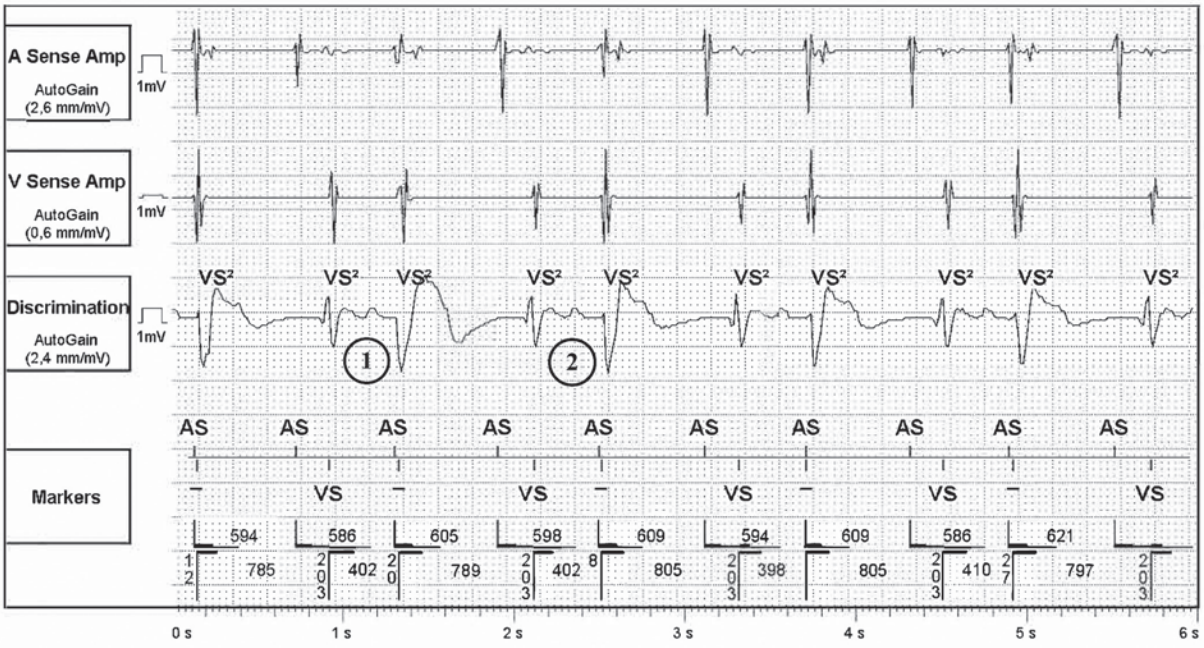
Episode: Non-sustained V Oversensing

5 Mar 2014 13:26

Mode n/a

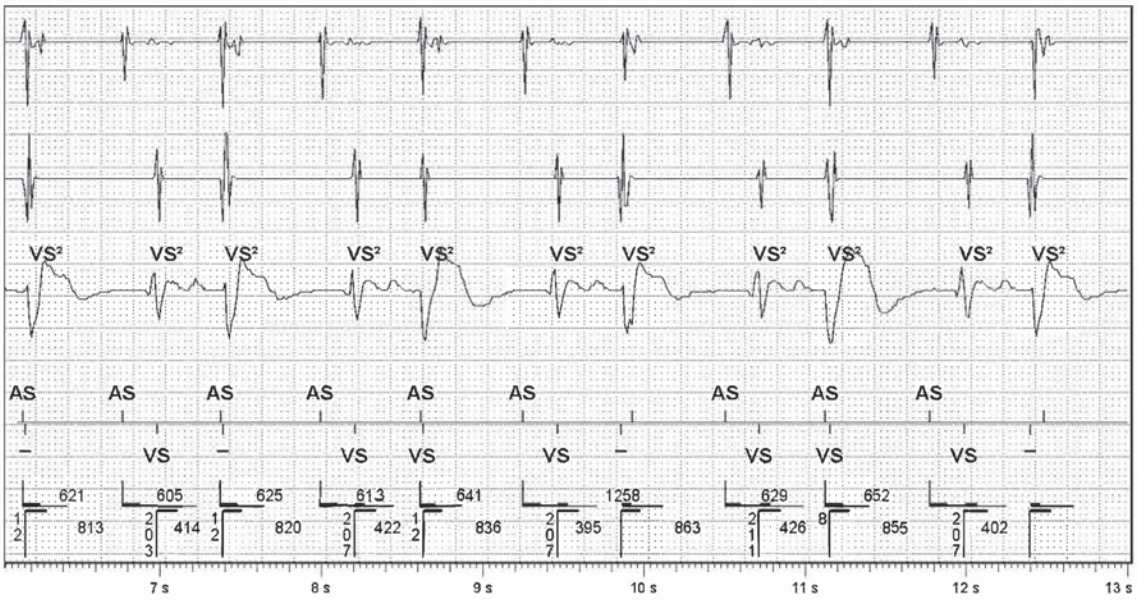
1: A Sense Amp AutoGain (2,6 mm/mV)
2: V Sense Amp AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (2,4 mm/mV)
4: Markers

Sweep Speed: 25 mm/s



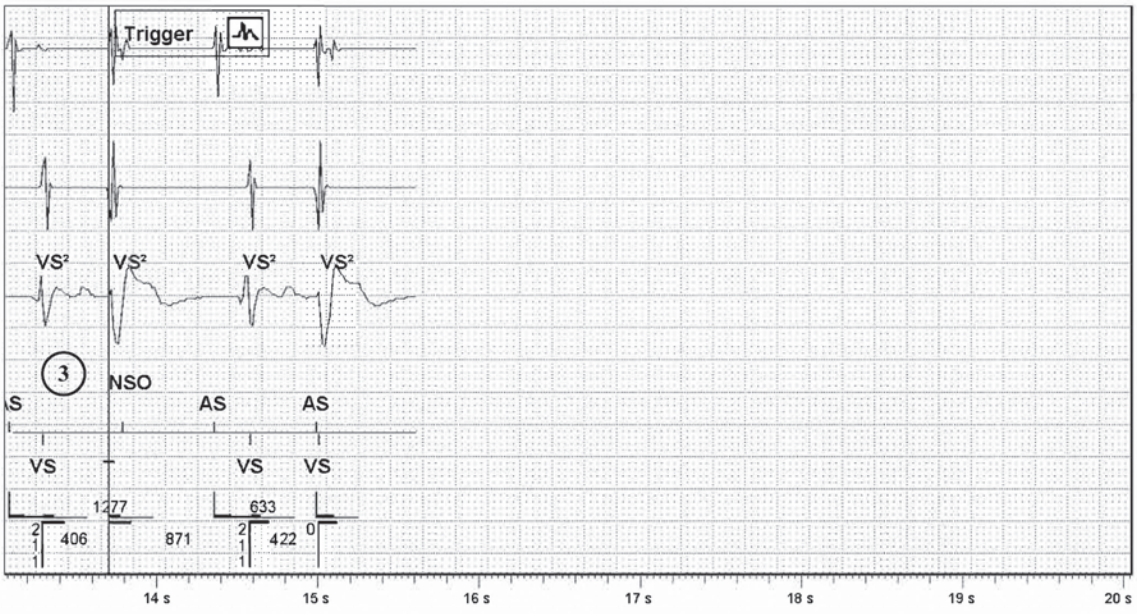
Episode: Non-sustained V Oversensing (Continued)

5 Mar 2014 13:26



1: A Sense Amp AutoGain (2,6 mm/mV)
2: V Sense Amp AutoGain (0,6 mm/mV)
3: Discrimination AutoGain (2,4 mm/mV)
4: Markers

Sweep Speed: 25 mm/s



Tracing 9: SecureSense™ algorithm and undersensing on the discrimination channel

Patient

This 77-year-old man received a Quadra Assura™ triple chamber defibrillator for the management of ischemic cardiomyopathy with permanent AF. Episodes of non-sustained RV oversensing were stored in the device memory.

Tracing 9A

1: biventricular stimulation;
2: premature ventricular contraction triggering a ventricular tachyarrhythmia; first short cycle on the bipolar channel;
3: second short cycle; activation of the noise counter 350 ms after this second cycle;
4: first T-classified cycle on the bipolar channel; absence of VS2 marker on the discrimination channel, while the warm-up phase is over, indicative of undersensing on this channel;
5: first cycle detected on the discrimination channel;
6: undersensing on the discrimination channel followed by second cycle detected without prominent pause between the 2 VS2 markers;
7: same sequence;
8: the noise counter is at 10 (10 short cycles on the bipolar channel) whereas the VF or VT counter is not filled; diagnosis of non-sustained ventricular oversensing (SNS); the noise counter was not reinitialized in view of the absence of short cycles on the discrimination channel. Diagnostic error by the device; spontaneous termination a few cycles later.

Patient

This 71-year-old man received an Ellipse™ VR defibrillator for the management of ischemic cardiomyopathy. An episode of VT was stored in the device memory.

Tracing 9B

1: diagnosis of undersensing on the discrimination channel. The SecureSense™ algorithm was automatically switched to "Passive";
2: VS classified cycles with poor quality of sensing on the discrimination channel (low-amplitude signals, 1 mV for 10 mm amplification, <0.5 mV ventricular signals on this channel);
3: acceleration of the rate with T classified cycles;
4: the VT counter is full (16);
5: burst;
6: successful burst and return to sinus rhythm diagnosed after 3 consecutive VS cycles;

Comments

The preservation of the highest sensitivity to the detection of ventricular arrhythmias is an absolute requirement of all algorithms that may inhibit the therapies. The SecureSense™ algorithm includes a protection against undersensing on the discrimination channel. The algorithm is withheld if ≥1 event among the following 3 is observed during an episode:
1) ≥2 VS2 cycles with a < 0.6 mV amplitude; 2) >2,200 ms pause between 2 VS2 cycles; 3) detection of a single cycle on the discrimination channel. The SecureSense™ algorithm is automatically reprogrammed to "Passive" during an episode and an undersensing alert appears on the programmer. During a sustained ventricular tachyarrhythmia, 3 situations are, therefore, possible depending on the quality of sensing on the discrimination channel:
- if sensing is of good quality, the occurrence of short cycles on the discrimination channel regularly reset the noise counter to 0 and the therapies are not inhibited by the algorithm;
- if the quality of sensing is poor (second tracing), a) at least 1 of the 3 criteria is filled, b) the

SecureSense™ algorithm is interrupted and reprogrammed to "Passive", c) an alert appears on the programmer, and d) the therapies are not inhibited by the algorithm;
- in very rare cases, undersensing is intermittent (first tracing) with a risk of inappropriate inhibition of the therapies. However, this risk is very low and, in a large study carried out in our medical center, we observed no prolonged inhibition of the therapies that might have threatened the patients' well-being. The risk of undersensing an episode for a long duration while not fulfilling at least one of the previously described criteria is very low.

When the sensing quality on the discrimination channel is not flawless, the sensing settings on the discrimination channel cannot be changed (blanking, threshold start, decay delay, and ventricular sensitivity are not programmable). It is, on the other hand, possible to reprogram the discrimination channel on Tip to Can, which also modifies the Morphology Far-Field vector applied in the discrimination. The integration of the distal electrode in the sensing vector to the discrimination channel may, however, limit the algorithm in its ability to prevent the delivery of inappropriate therapies due to lead dysfunction, since the distal electrode is included in the 2 (bipolar and discrimination) sensing vectors. Discordance between the 2 vectors is then less likely if the dysfunction involves the distal electrode. Another solution, in the rare cases of undersensing, consists of programming the algorithm on "Passive", which will eliminate the risk of inappropriate inhibition of the therapies.

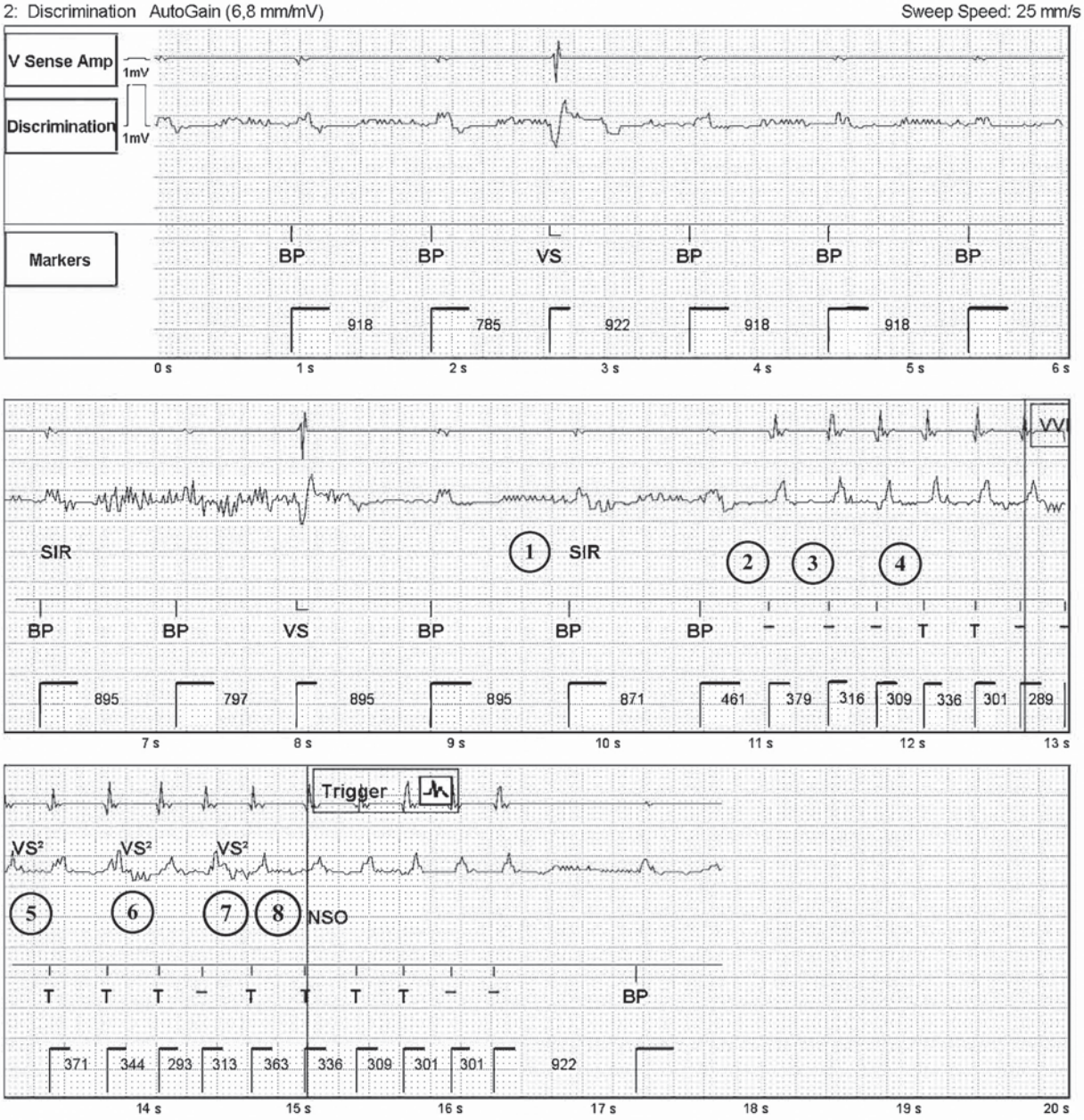
Episode: Non-sustained RV Oversensing

31 Jan 2015 8:56

Mode VVIR

1: V Sense Amp AutoGain (0,4 mm/mV) 3: Markers
2: Discrimination AutoGain (6,8 mm/mV)

Sweep Speed: 25 mm/s



ST. JUDE MEDICAL

4 Jun 2014
15:43
Archive

Episode: VT (181 bpm / 330 ms)

VT/VF Episode 6 of 8
Page 1 of 3

27 Feb 2014 0:53

Duration	00:14 (M:S)	**Alerts**	**SVT discriminators disagree**
Detection Criteria	171 - 221 bpm	⚠	**Undersensing was detected on the SecureSense™ channel, and SecureSense™ was changed to Passive**

Therapy	**Results**
1) ATP	1) Below Rate Detection (CL 795 ms)

(1)

ATP Therapy Details
VT ATP Therapy

Successful BCL 280 ms
Therapy 1
Burst 1 280, 280, 280, 280, 280, 280, 280 ms

Diagnosis Summary

	Diagnosis
	VT
Time to Diagnosis	5,25 sec
Rate (CL)	181 bpm (330 ms)
Zone	VT
VT Diagnosis Criteria	2 of 3
Morphology	On, ≥ 90% is a match, ≥ 3 matches indicate SVT
Min Match Score	n/a
Max Non-Match Score	0%
No. Template Matches	0 of 10 **(VT Indicated)**
Sudden Onset	On, < 16 % indicates SVT
Max Delta	36 % **(VT Indicated)**
Interval Stability	On w/SIH, ≥ 40 ms or SIH Count ≥ 2 intervals indicates SVT
Stability Delta	55 ms **(SVT Indicated)**

SVT Criteria Statistics
SVT Diagnoses during this episode 0

Measured SVT Discriminator values through initial VT/VF Diagnosis

Min Match Score	n/a	Min/Max Stability Delta	55 ms /55 ms
Max Non-Match Score	0 %	Template Used	5 May 2013 17:58
Max Onset Delta	36 %		

DeFT Response™ Settings (Shock Waveform)			**1st Phase**	**2nd Phase**
Waveform	Biphasic	VF Shocks (Defib)	65 %	65 %
Waveform Mode	Tilt	VT Shocks (CVRT)	Same as Defib	Same as Defib
Shock Configuration	RV to SVC & Can			
RV Polarity	Anode(+)			
Defib Max Sensitivity	0.5 mV			

ST. JUDE MEDICAL

4 Jun 2014
15:43
Archive

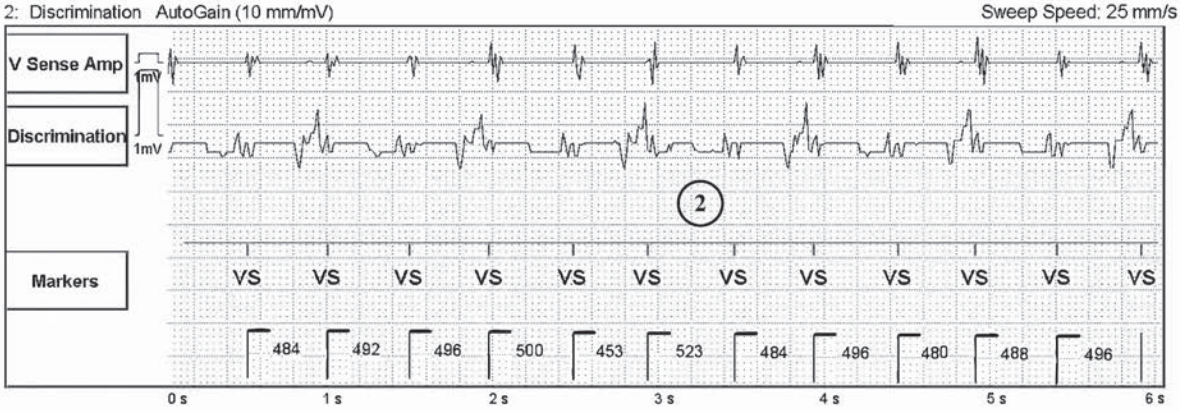
Episode: VT (181 bpm / 330 ms)

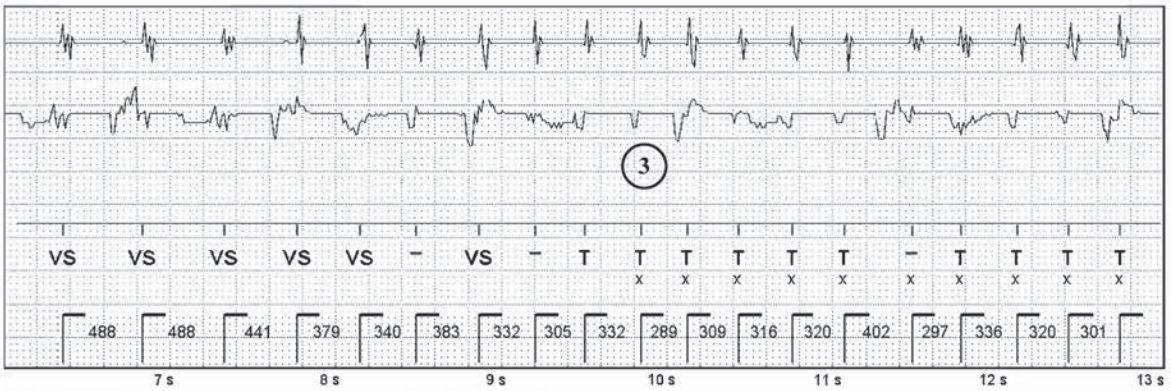
27 Feb 2014 0:53

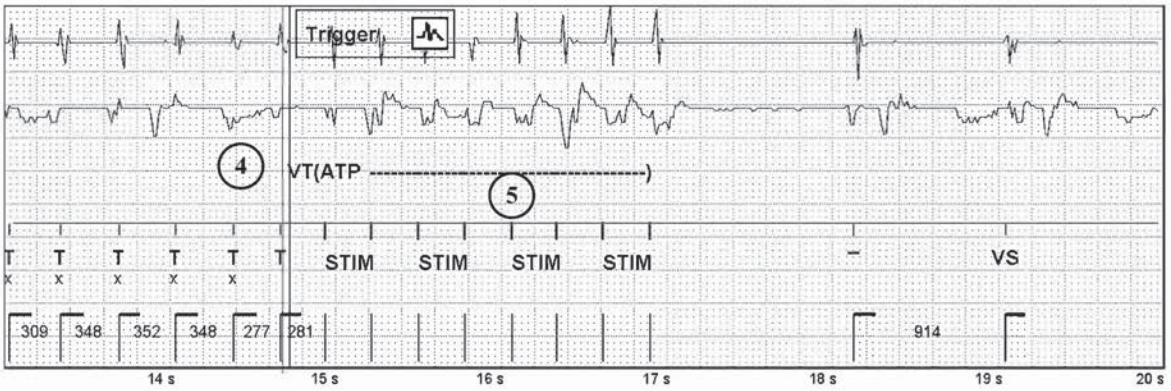
VT/VF Episode 6 of 8
Page 2 of 3

1: V Sense Amp AutoGain (1,6 mm/mV)
2: Discrimination AutoGain (10 mm/mV)
3: Markers

Sweep Speed: 25 mm/s







ST. JUDE MEDICAL

4 Jun 2014
15:43
Archive

Episode: VT (181 bpm / 330 ms) (Continued)

27 Feb 2014 0:53

VT/VF Episode 6 of 8
Page 3 of 3

1: V Sense Amp AutoGain (1,6 mm/mV)
2: Discrimination AutoGain (10 mm/mV)
3: Markers

Sweep Speed: 25 mm/s