

Dr M. STRIK

Dr K. MAHFOUZ

Pr P. BORDACHAR

D. GROSMIRE

Dr P. RITTER

Pacemaker

clinical cases based on

MicroPort™ devices



2022 Edition



Pacemaker

clinical cases based on tracings from **MicroPort™**

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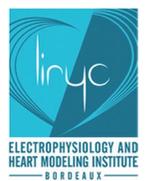
Dr M. STRIK

Dr K. MAHFOUZ

Pr P. BORDACHAR

D. GROSMIRE

Dr P. RITTER





Have contributed to the writing of this book:

R. Chauvel - CHU Bordeaux, IHU Liryc

S. Garrigue - Clinique St Augustin Bordeaux

L. Brochard - MicroPort™

N. Klotz - CHU Bordeaux, IHU Liryc

N. Iscolo - MicroPort™

S. Ploux - CHU Bordeaux, IHU Liryc

S. Reuter - Clinique St Augustin Bordeaux

M. Strik - CHU Bordeaux, IHU Liryc

A. Ximenes - Ch St Palais



Foreword.....	11
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Chapter 1 - Pacemaker 13

Tracing 1: ODO Mode.....	16
Tracing 2: DOO Mode 40 beats/minute.....	20
Tracing 3: DOO Mode 70 Beats/minute.....	22
Tracing 4: AAT Mode 40 Beats/minute.....	26
Tracing 5: AAT Mode 60 Beats/minute.....	28
Tracing 6: VVT Mode 40 Beats/minute.....	30
Tracing 7: AAI Mode 30 Beats/minute.....	34
Tracing 8: AAI Mode 60 Beats/minute.....	36
Tracing 9: VVI Mode 60 Beats/minute.....	40
Tracing 10: VVI Mode 40 Beats/minute.....	42
Tracing 11: VDD Mode 60 Beats/minute.....	46
Tracing 12: DDI Mode 60 Beats/minute.....	50
Tracing 13: DDD Mode 60 Beats/minute.....	54
Tracing 14: SafeR Mode 60 Beats/minute.....	58

Chapter 2 - SafeR Mode 61

Tracing 15: First-degree AV block (AVB I) criterion.....	64
Tracing 16: AVB I criterion.....	68
Tracing 17: Second-degree AV block (AVB II) criterion.....	72
Tracing 18: Third-degree AV block (AVB III) criterion.....	76
Tracing 19: Pause criterion.....	80
Tracing 20: DDD-ADI switching.....	84
Tracing 21: DDD-ADI switching.....	86
Tracing 22: Inappropriate AVB I criterion.....	90
Tracing 23: Inappropriate AVB II criterion.....	94
Tracing 24: Inappropriate AVB II criterion.....	96
Tracing 25: Inappropriate pause criterion.....	100
Tracing 26: Inappropriate pause criterion (PVC).....	102

Chapter 3 - Pacing 105

Tracing 27: Capture failure.....	108
Tracing 28: Atrial capture failure.....	112
Tracing 29: Atrial capture failure.....	118

Chapter 4 - Sensing 123

Tracing 31: Atrial sensing failure.....	126
Tracing 32: Atrial sensing failure 2.....	128
Tracing 33: Ventricular sensing failure.....	132
Tracing 34: AF undersensing.....	138
Tracing 35: Noise.....	142

Chapter 5 - Atrioventricular Delay and Refractory Periods 145

Tracing 36: Refractory Periods.....	148
Tracing 37: Refractory Periods 2:1 flutter.....	152
Tracing 38: WARAD + retroPwatch.....	156
Tracing 39: WARAD + retroPwatch.....	160
Tracing 40: PMT.....	164
Tracing 41: Post atrial ventricular blanking (PAVB).....	170

Chapter 6 - Exercise programming 173

Tracing 42: Programming atrial sensitivity and exercise.....	176
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Chapter 7 - Arrhythmia management	179
Tracing 43: mode switch	182
Tracing 44: NSVT	188
Tracing 45: Apnea	192
Chapter 8 - Rate smoothing, AV delay and PMT	195
Rate Smoothing.....	196
Automatic AV delay.....	198
Anti-pacemaker medicated tachycardia algorithm.....	201
Chapter 9 - MicroPort™ pacemakers in 20 points	205



Reading this educational book will allow you to acquire the basics necessary to use the pacemakers of the MicroPort™ brand. This company is mainly the result of a fusion between the French manufacturer Ela Médical™ and its Italian counterpart Sorin Biomedical™, which took place in 2004. The owner is now Chinese and the company is now called MicroPort™.

It is important to remember that the technology and intelligence of the pacemakers we use today are the result of ideas and development carried out by Ela Médical™'s Research and Development teams. All the algorithms that form the basis of the operation of the stimulators were developed in close collaboration with a number of stimulating physicians, mainly French. These algorithms constitute the very basis of all modern pacemakers, such as protection against electronic reentrant tachycardias, protection against atrial arrhythmias, rate control based on the combination of minute ventilation measurement and body accelerations, adaptable atrio-ventricular delay, preservation of spontaneous atrio-ventricular conduction, functions to prevent atrial arrhythmias and registering of arrhythmias. The intelligence of the Sorin teams led by Guido Gaggini was not to dismantle what made the technological success of Ela Médical™.

I had the pleasure of working with these brilliant teams and of seeing all these functions copied by competing manufacturers, proof that we were not just developing gadgets.

A basic idea governed the constitution of these functions and their association. The idea was to make the device as autonomous as possible by automatically managing the various

functions between them, and the various operating conflicts that could arise, with a single aim: to simplify the task of the users that we are and to ensure the safety of the patient by managing the foreseeable complications linked to the operation of a complex device such as a double chamber stimulator for example. This explains why MicroPort™ pacemakers have fewer programmable parameters than their competitors, in order to guarantee the systematic and simple use of algorithms.

This book, like all those in the Stimuprat series, brings together, in a logical and didactic way, and with increasing complexity, electrocardiographic tracings and electrograms collected during our consultations, aimed at educating the reader in the operation and use of the various functions of the MicroPort™ stimulation devices. It is thanks to the work of Karim Mafhouz, an Italian colleague and Marc Strik, a Dutch cardiologist, and under the guidance of Pierre Bordachar, that this book was made possible. In this task, a number of members of the MicroPort™ teams have actively participated in guiding the doctors on purely technical subjects. Nicolas Iscolo, Damien Grosmaire, Laurent Minjard, Sarah Cremades, Nicolas Rosset, Leslie Brochard, Rami El Khechen, Christèle Deniaud are warmly thanked for their precious help. I am proud to have belonged, and to belong to this chain of actors guided by passion, the pleasure to develop in community, and to transmit their experience!

Enjoy your reading.

Philippe Ritter



Pacemaker **chapter 1**

Pacing Modes



Patient

69-year-old man, implanted with a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; both leads are well positioned with normal pacing impedances, proper sensing and satisfactory pacing thresholds; the day after implantation, pacemaker control; programming of different pacing modes and recording of the tracings;

Quiz

Regarding this ECG, what is(are) the correct answer(s)?

- A. the rhythm is sinus
- B. the atria are paced
- C. the ventricles are paced
- D. there is a left anterior fascicular block
- E. there is a right bundle branch block



TRACING

ODO mode: sinus rhythm at 60 beats/minute; normal and fixed PR interval (< 200 ms); intrinsic ventricular activity with right bundle branch block pattern (QRS 140 ms, rSR' pattern in V1 with delayed intrinsicoid deflection, wide and slurred S wave in V6); the As marker corresponds to the sensing of intrinsic atrial activity, the Vs marker to the sensing of intrinsic ventricular activity; on the atrial channel, the imprint of intrinsic ventricular activity can be observed in conjunction with R wave sensing in the ventricular channel; this signal is not sensed in the atrial channel;

COMMENTS

Depending on the number of leads and the implanted device model, different pacing modes are programmable. The operation as well as the advantages and disadvantages specific to each pacing mode must be understood by the physician providing the (follow-up) in order to optimize the programming relative to the specificities of the implanted patients. A combined approach between the North American Society and the British Society of Pacing and Electrophysiology (NASPE and BPEG) has allowed defining an international classification code (NBG) for the different pacing modes. The various pacing modes are qualified by a 4-letter code enabling to understand their basic operation. The first letter defines the pacing site(s): ventricle (V), atrium (A), both (D), single-chamber (S) or none (O). The second letter defines the sensing site(s): same letters. The third letter indicates the operating mode: inhibited (I), triggered (T), both (D), none of the previous (O). The fourth letter indicates the rate response (R) or its absence (O).

On this first tracing, the pacemaker was programmed in ODO mode. The specificity of this "pacing" mode is that sensing in both chambers is effective whereas pacing (atrial or ventricular) is deactivated. This mode is therefore to be avoided in pacemaker-dependent patients. This pacing mode enables an analysis of the intrinsic rhythm of the patient with concomitant visualization of the electrocardiogram and event markers. This is a sensitivity test mode. The ODO mode can be programmed temporarily for non-dependent patients with an MRI-compatible pacemaker who are scheduled to undergo an MRI. The ODO mode of these compatible MRI pacemakers prevents the possible reversion of a conventional ODO mode to a VVI mode. Obviously, one must not forget to re-monitor and reprogram the pacemaker after the MRI exam (depending on the manufacturer).

Specificities; D00 mode: no sensing capability, asynchronous pacing; ODO mode: no pacing; DDT mode: triggered mode, sensing triggers pacing; VDD mode: no atrial pacing; DDI mode: no ventricular pacing following atrial sensing; DDD mode: ventricular synchronization on atrial sensing and ventricular pacing; modes specific to each manufacturer to avoid unnecessary ventricular pacing.



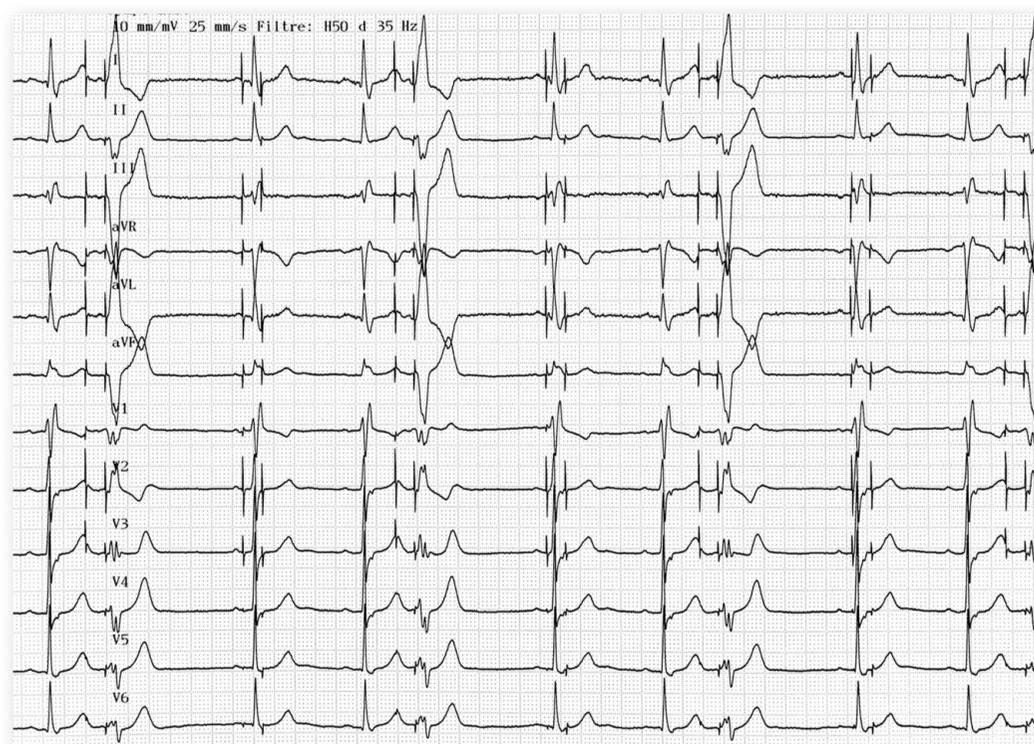
Patient

Same patient as in the previous tracing;

Quiz

Which mode is compatible with this tracing?

- A. DDD 60 bpm
- B. DDI 40 bpm
- C. DDI 70 bpm
- D. DDO 40 bpm
- E. DDO 70 bpm



TRACING

DDO mode 40 beats/minute: on this tracing, one can observe regular atrial (A) and ventricular (V) pacing at a rate of 40 bpm; atrial and ventricular capture is effective only when occurring outside myocardial refractory periods (atrial and ventricular); this pacing is asynchronous, atrial and ventricular activities are by definition undetectable and therefore cannot inhibit pacing.

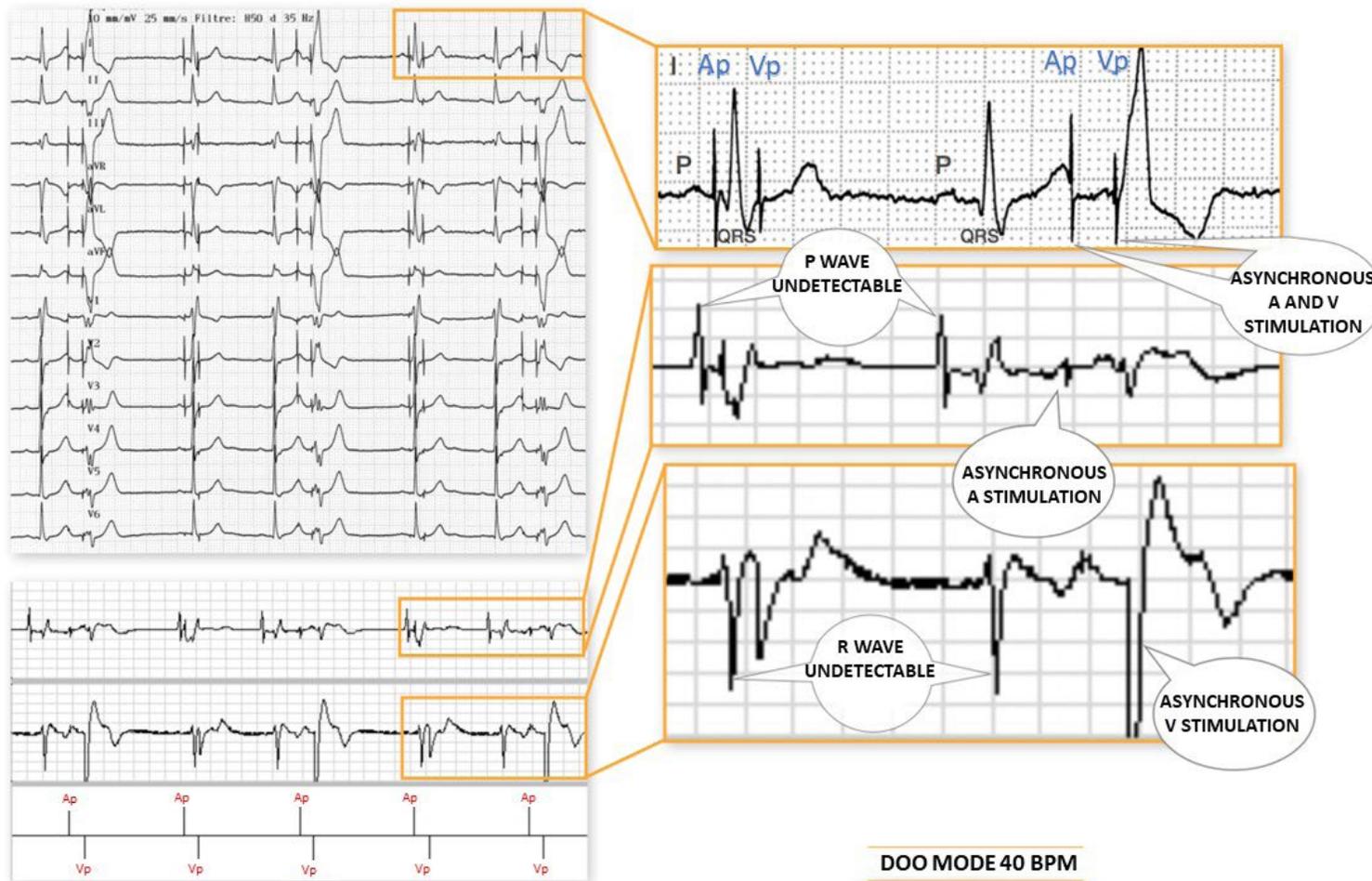
COMMENTS

The operation of the DDO mode is the opposite of the ODO mode: there is no sensing with pacing at fixed intervals. Asynchronous fixed rate modes were the only modes available on the first pacemakers. The DDO mode induces sequential asynchronous atrioventricular pacing, without inhibition by intrinsic events. When the patient is not device-dependent, parasystole occurs with competition between intrinsic activities and paced activities, especially since the programmed minimum rate is low. This mode allows to verify pacing effectiveness and avoiding inhibition upon exposure to external interference (electrosurgery in a pacemaker-dependent patient for example). Pacing is effective and captures atrial or ventricular activity only when it occurs outside the absolute physiological refractory period following an intrinsic atrial or ventricular activity. When ventricular pacing occurs during the vulnerable period, there is a risk of inducing a ventricular rhythm disorder. While the risk of ventricular fibrillation is limited, it does increase however in the presence of myocardial ischemia or metabolic disorder. In the same manner, asynchronous atrial pacing in the vulnerable atrial period can also induce atrial fibrillation.

Asynchronous modes are now obsolete and are only used in 2 specific circumstances:

1. magnet mode; indeed, the application of a magnet causes AOO, VOO or DDO pacing according to the programmed mode
2. the DDO mode can be programmed temporarily for pacemaker-dependent patients with an MRI-compatible pacemaker having to undergo an MRI.

Pacing in a vulnerable ventricular or atrial period can be arrhythmogenic and favor the occurrence of a ventricular or atrial arrhythmia, most often polymorphous in nature.



Tracing 3: DDO Mode 70 beats/minute

TRACING

DDO mode 70 beats/minute: pacing rate higher than the intrinsic rate of the patient; permanent atrial and ventricular capture;

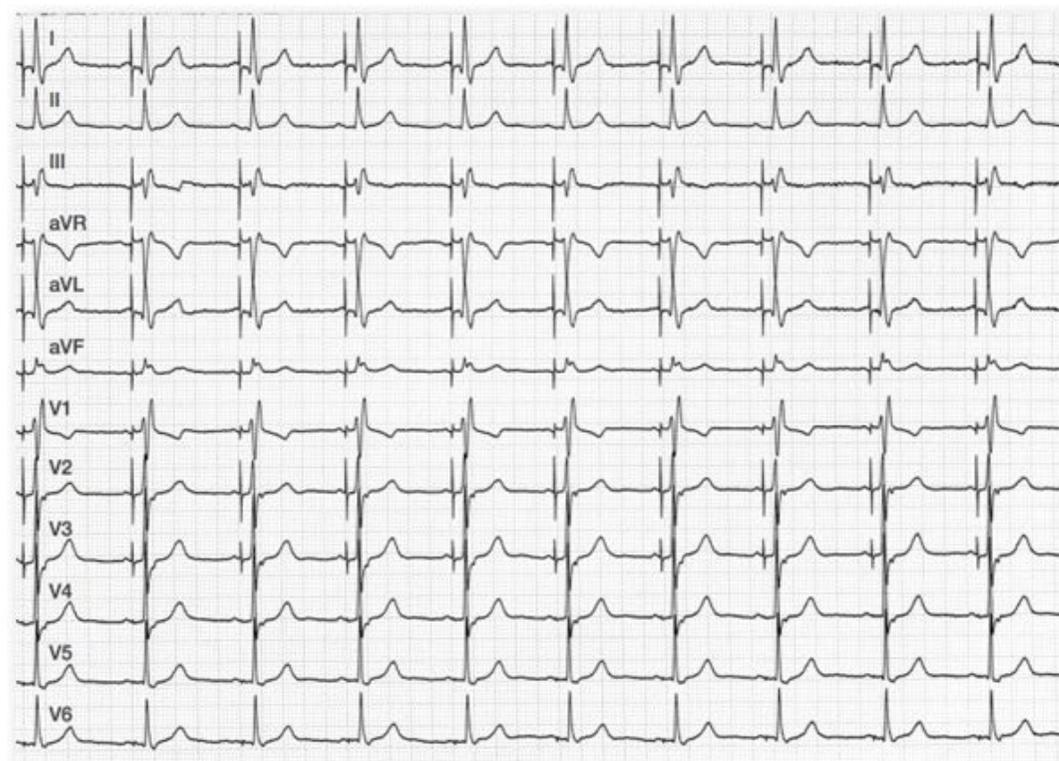
Patient

Same patient as in the previous tracing;

Quiz

Which mode is compatible with this tracing?

- A. AAI 60 bpm
- B. AAI 40 bpm
- C. AAT 70 bpm
- D. AAT 40 bpm
- E. VVT 50 bpm



TRACING

AAT mode 40 beats/minute: on this tracing, one can observe atrial pacing (An) triggered by atrial sensing (As); intrinsic ventricular activation;

COMMENTS

In AAT and VVT modes, pacing occurs at the programmed minimum rate; however an event sensed outside the refractory periods triggers an immediate pacing in the corresponding chamber. This pacing is not dangerous since systematically occurring in the absolute natural refractory period of the atrial or ventricular myocardium.

For MicroPort™ pacemakers, the 2 important parameters to program are the basic rate and the maximum rate. The only rate limitation is the non-programmable Fmax "hardware" (185 bpm).

Typical electrocardiographic pattern (VVT): in the absence of intrinsic activity, pacing and fixed-interval ventricular capture. The occurrence of an intrinsic ventricular complex outside the refractory periods leads to the occurrence of a stimulus within the QRS. The pattern of the QRS is either identical to the intrinsic QRS (pseudo-fusion), or intermediate between the intrinsic QRS and the paced QRS (fusion).

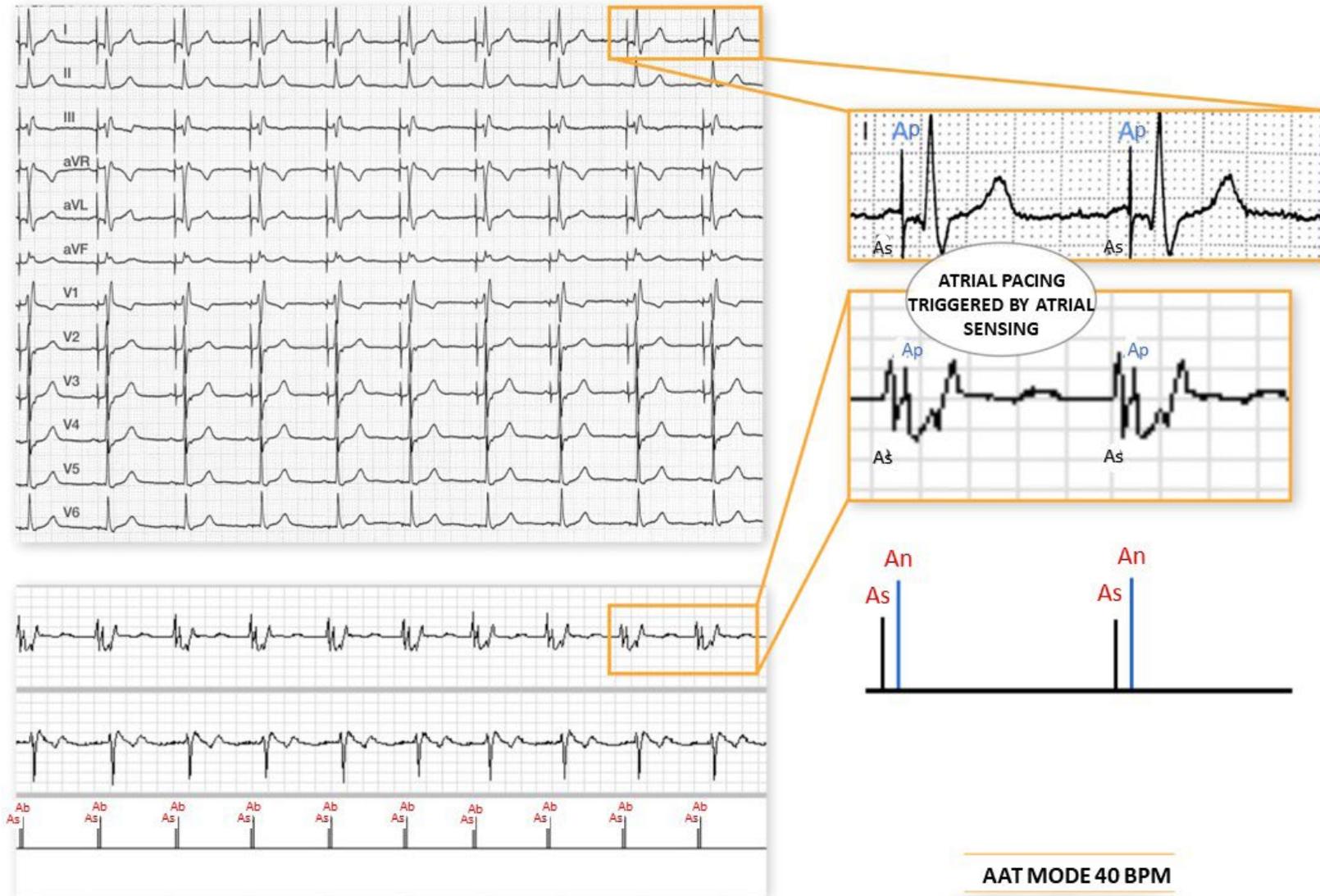
Note that the P wave is not sensed at the outset, but only after a few tens of ms. Detection is only possible when the atrial signal has passed under the lead dipole with a slope in the filter's bandpass and an amplitude \geq the programmed value.

Typical electrocardiographic pattern (AAT): the same for the atrium.

The triggered modes can be used in 2 particular instances:

1. upon sensing myopotentials or electromagnetic interference, the SST does not inhibit but rather induces pacing on each artifact sensed outside the refractory period. This avoids a pause in pacemaker-dependent patients. To prevent runaway pacing, it is possible to either extend the refractory period or to limit the maximum pacing rate depending on the model. This type of mode was of interest on older pacemaker models that were more sensitive to external interference since they only worked in unipolar mode.
2. this mode is used to evaluate sensing in the chamber under consideration, to verify that there is no crosstalk and that the extrasystoles are also properly sensed.

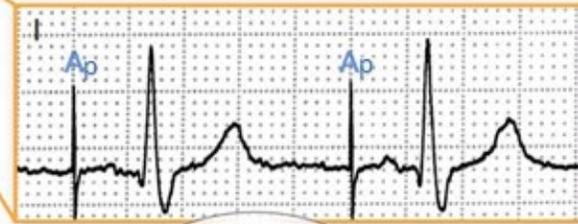
This type of pacing mode is rarely used today. Indeed, pacing during sensing is associated with an unnecessary increase in energy consumption with acceleration of battery depletion. AAT or VVT modes can be used temporarily to avoid inhibition in a pacemaker-dependent patient presenting oversensing. They can also be used to monitor the sensing quality during temporary tests.



Tracing 5: AAT Mode 60 beats/minute

TRACING

AAT mode 60 beats/minute: atrial pacing at the basic rate (A); the intrinsic sinus rate is lower than the pacing rate, atrial activity is fully captured.



**ATRIAL
PACING AT
LOWER RATE**

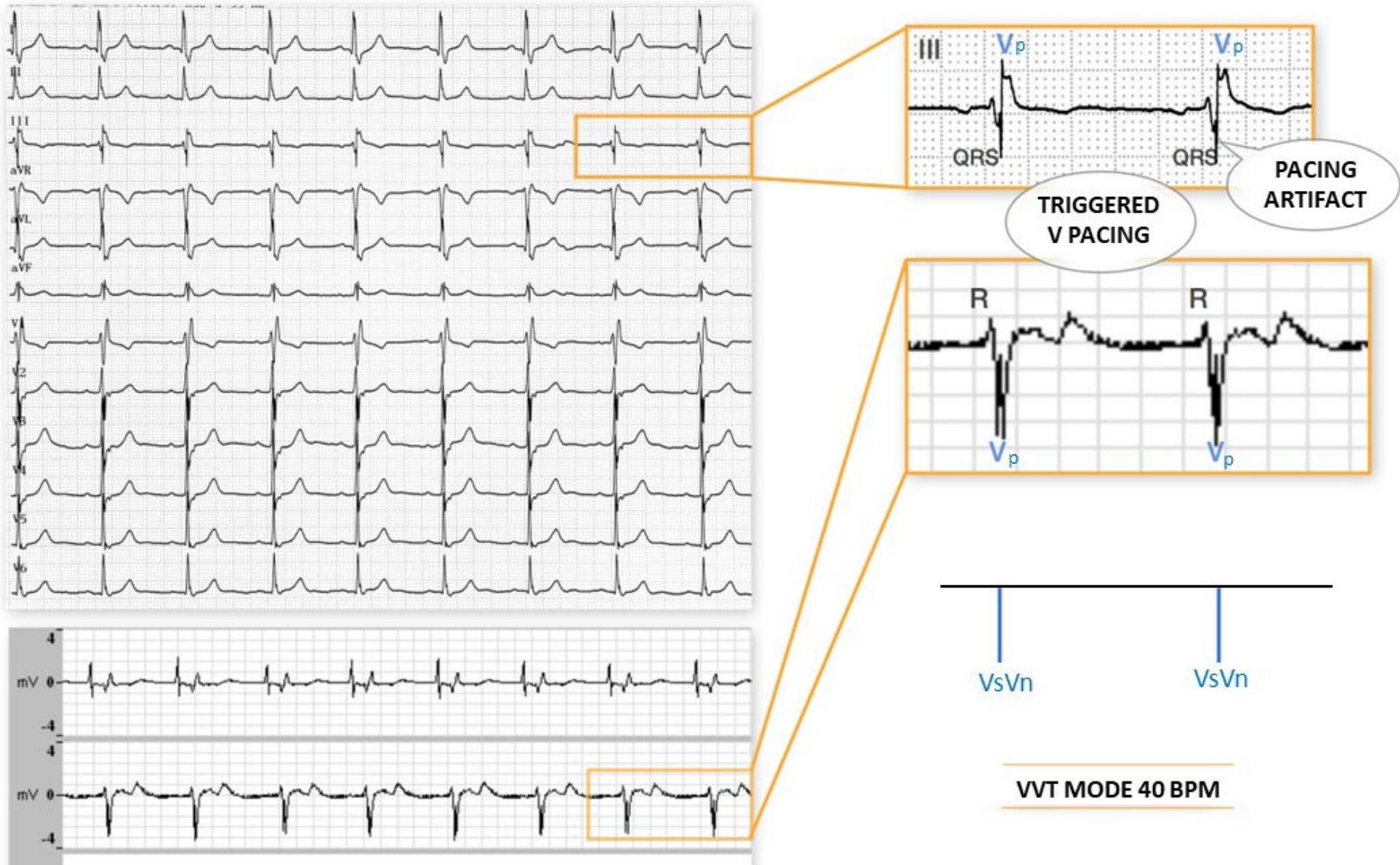


AAT MODE 60 BPM

Tracing 6: VVT Mode 40 beats/minute

TRACING

VVT Mode 40 beats/ minute: ventricular pacing (Vn) triggered by ventricular sensing (Vs): even more obviously than in the atrium in this patient, the QRS sensing is late in the R-wave due to right bundle branch block , with the lead implanted in the right ventricle.



Patient

62-year-old man implanted with a Kora 100 DR MicroPort™ dual-chamber pacemaker for sinus dysfunction; both leads are well positioned with normal pacing impedances, proper sensing and satisfactory pacing thresholds;

Quiz

Which mode is compatible with this tracing?

- A. AAI 60 bpm
- B. AAI 30 bpm
- C. AAT 70 bpm
- D. AAT 40 bpm
- E. VVT 50 bpm



TRACING

AAI mode 30 beats/minute: initially, sinus activity (P) is faster than the minimum rate; first sinus pause with junctional escape; second pause with atrial pacing (Ap) after 2 seconds which corresponds to the minimum rate;

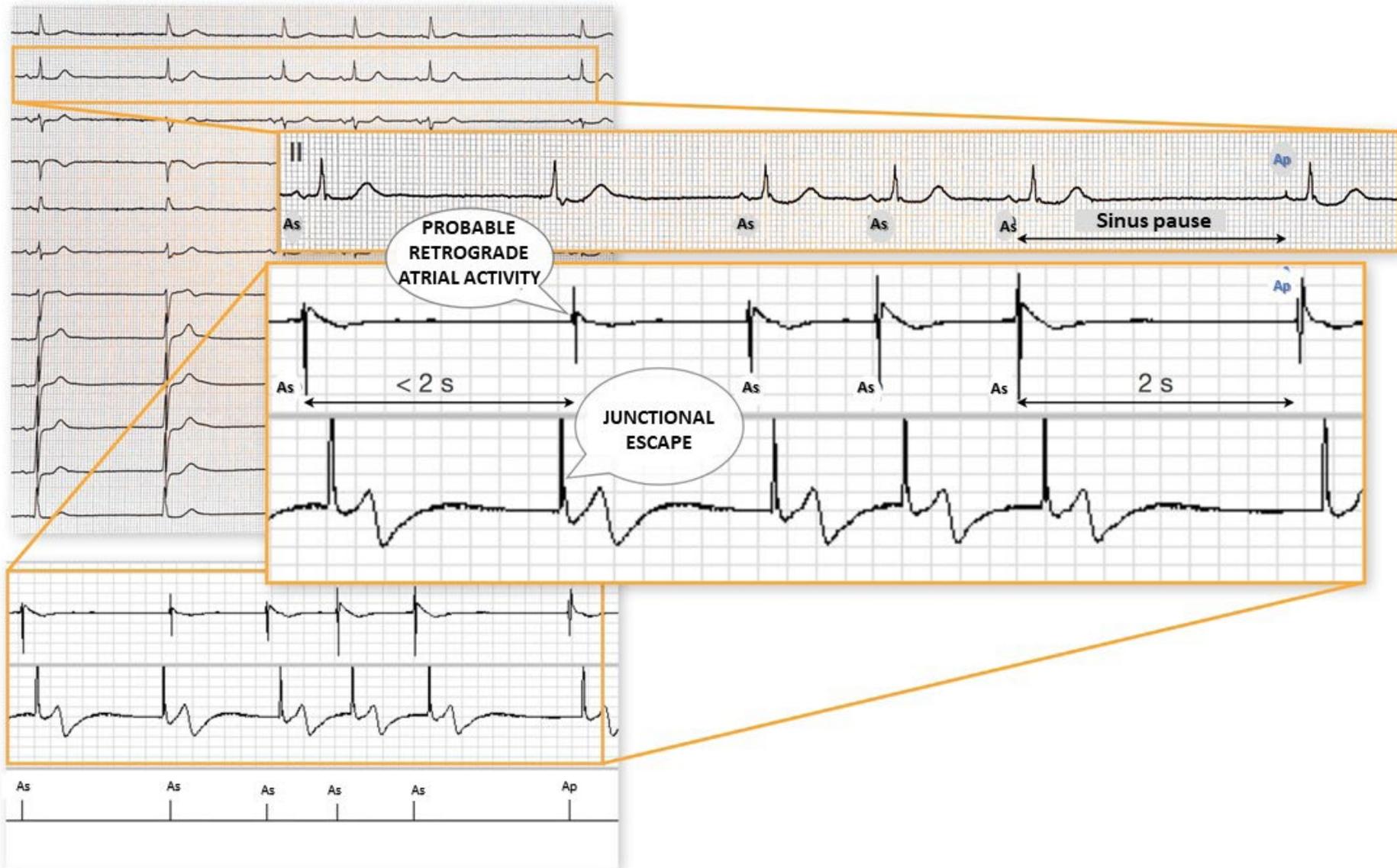
COMMENTS

A single-chamber pacemaker operates in AAI mode when only one lead is positioned in the atrium; AAI mode can also be programmed in a dual-chamber pacemaker. These tracings allow to highlight the main characteristics of this pacing mode:

- sensing and pacing of the atrium, inhibition on an intrinsic atrial event; the preferred indication is therefore pure sinus dysfunction without ventricular conduction disorder. An AAI pacemaker allows 1) to limit the number of implanted leads, 2) to ensure a physiological rate both at rest and during exercise after programming the rate response function and 3) to avoid any unnecessary ventricular pacing.
- absence of ventricular sensing or pacing. Single-chamber AAI pacemakers or AAI mode programming on a dual-chamber pacemaker are formally contraindicated in patients with permanent or paroxysmal atrioventricular conduction disorder. Similarly, it is preferable not to use the AAI mode in instances of long PR interval, intraventricular conductive disorder, low Luciani-Wenckebach point, long HV. This mode should also be avoided in patients with vagal symptoms or carotid sinus syndrome.

A recent study reported unfavorable results for the implantation of a single-chamber AAI pacemaker compared to the implantation of a dual-chamber pacemaker in patients with sinus dysfunction. Indeed, the rate of re-intervention is greater in patients implanted with an AAI pacemaker with the need to add a ventricular lead secondary to the occurrence of an atrioventricular conduction disorder. Current indications for implantation of a single-chamber pacemaker AAI are therefore relatively limited.

When the pacemaker operates in AAI mode, it may be necessary to program a higher sensitivity (lower programmed value) than for VVI operation; indeed, the amplitude of the atrial complexes is most often weaker than that of the ventricular complexes. Similarly, the refractory period may be programmed longer to prevent ventricular oversensing by the atrial lead. The sensing of an R wave by an AAI pacemaker causes a decrease in the pacing rate, because each sensed R wave recycles the escape interval. In the presence of far-field (sensing of the R wave) it is possible to lower the sensitivity of the pacemaker and/or to prolong the refractory period to encompass ventricular activity.

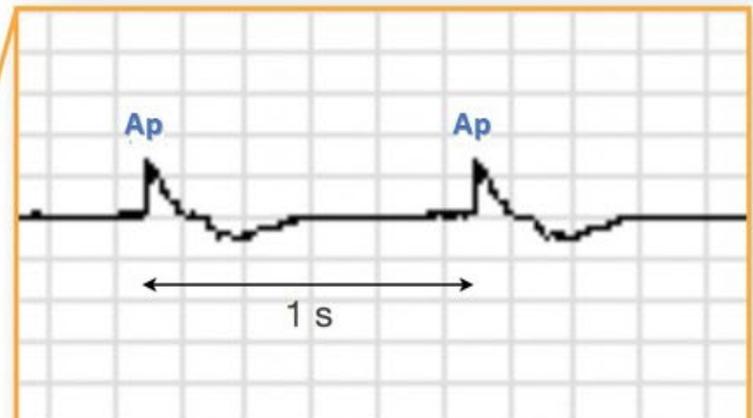
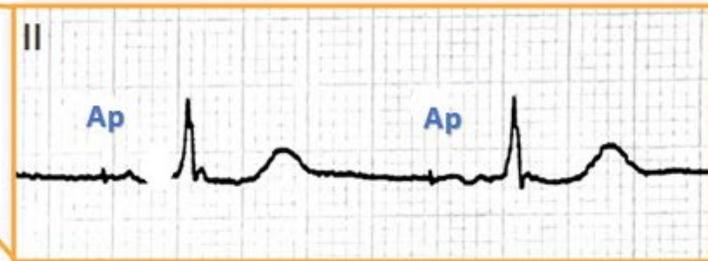
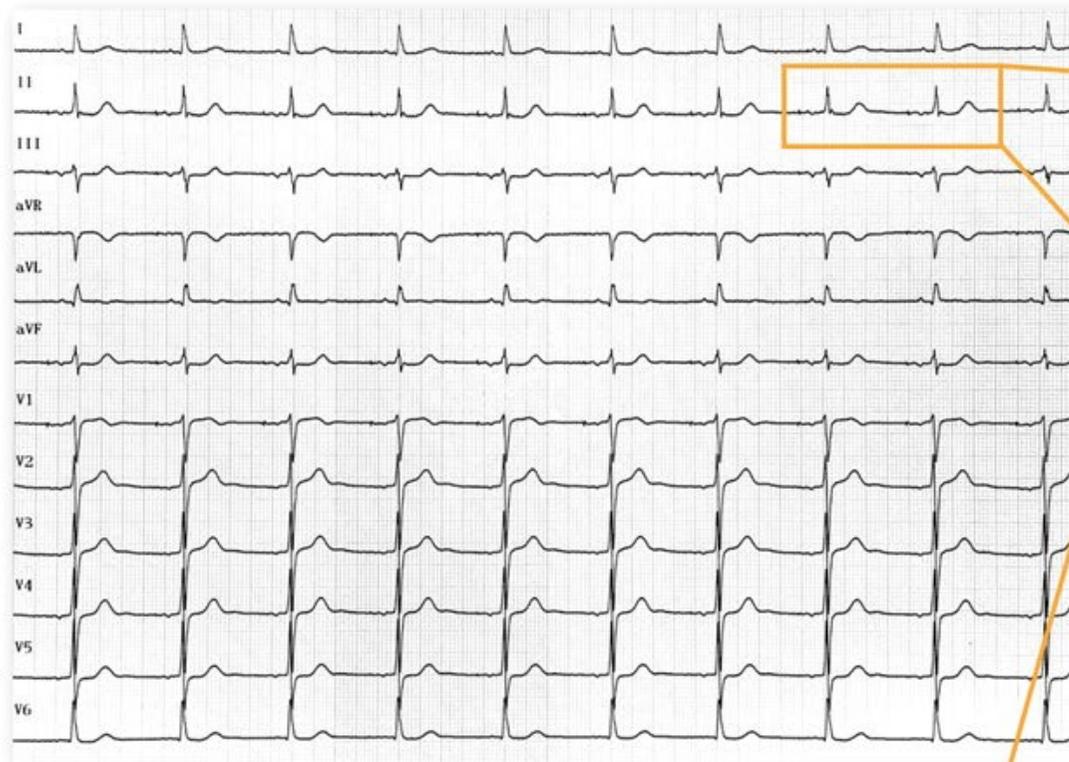


AAI MODE 30 BPM

Tracing 8: AAI Mode 60 beats/minute

TRACING

AAI mode 60 beats/minute: atrial pacing at the minimum rate (1 second escape interval) faster than the intrinsic sinus activity; intrinsic atrioventricular conduction;



AAI MODE 60 BPM

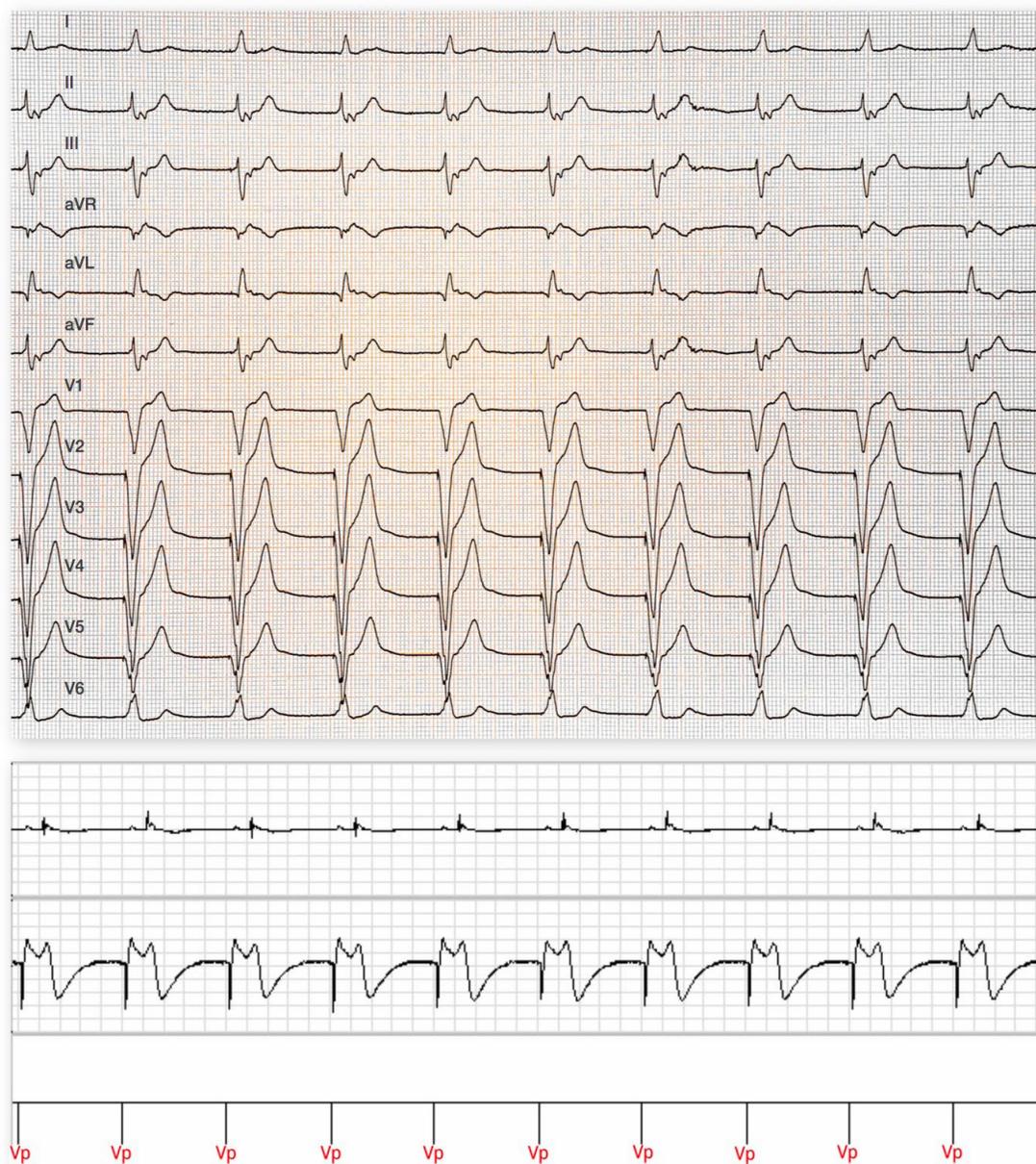
Patient

Same patient as in the previous tracing;

Quiz

Which mode is compatible with this tracing?

- A. VVI 60 bpm
- B. VDD 40 bpm
- C. DDI 60 bpm
- D. VVT 40 bpm
- E. VOO 40 bpm



TRACING

VVI mode 60 beats/minute: on this tracing, regular ventricular pacing at 60/min; in addition, there is a 1:1 retrograde atrial activation with a negative P' wave in the inferior leads;

COMMENTS

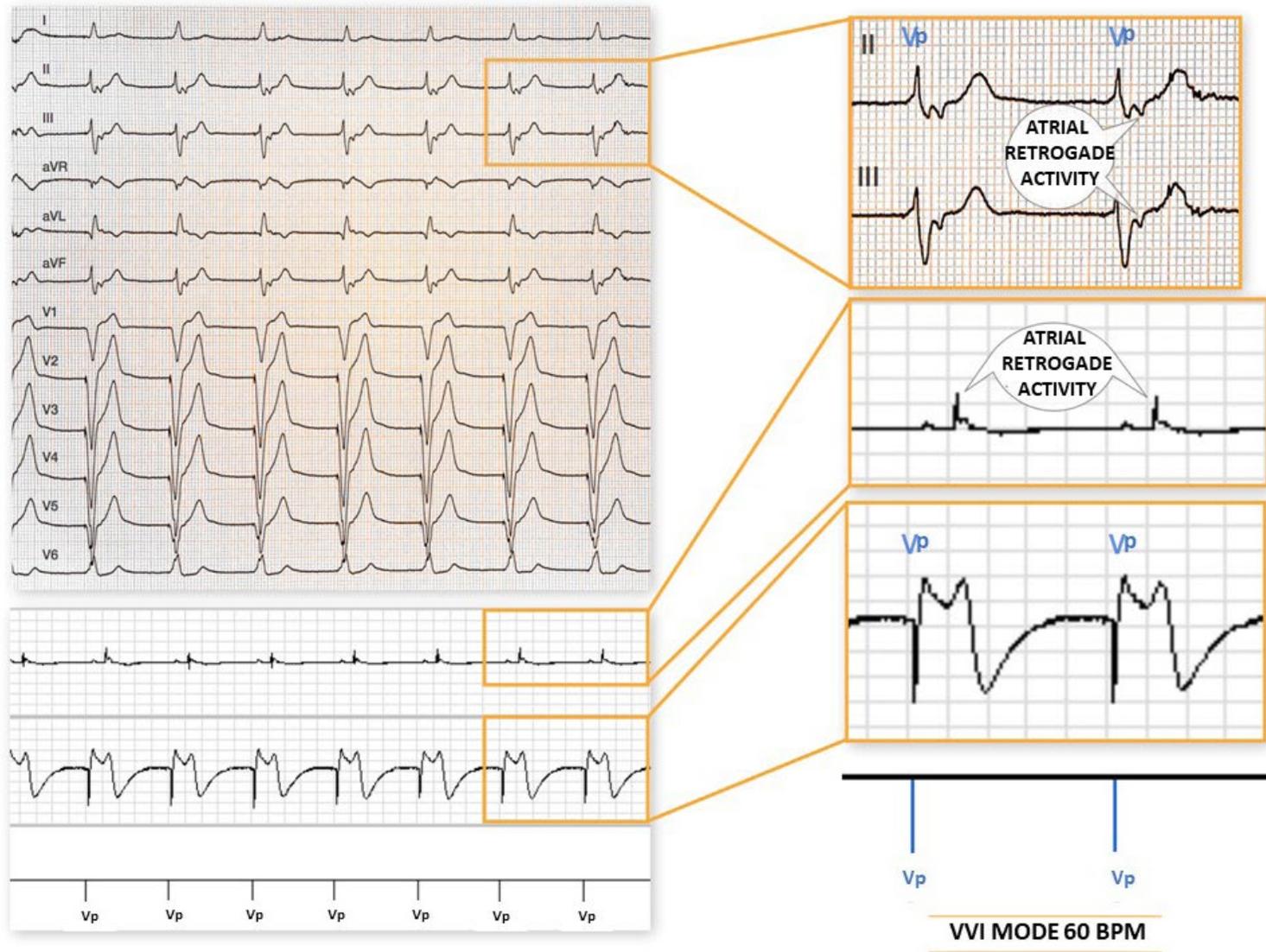
VVI mode provides single-chamber pacing at the programmed pacing rate, unless inhibited by a sensed event. Sensing only applies to the ventricle. An escape interval begins after any ventricular sensing and pacing. A single-chamber pacemaker operates in VVI mode when only one lead is positioned in the ventricle; VVI mode can also be programmed in a dual-chamber pacemaker as in the present example.

For this patient, programming the basic rate is essential. Indeed, at 60 bpm, the basic rate is too high and there is permanent ventricular pacing with inversion of the physiological atrioventricular activation sequence. Indeed, the electrocardiogram highlights a retrograde conduction with possible pacemaker syndrome. The atrial contraction occurs while the atrioventricular valves are closed causing a retrograde flow to the pulmonary veins and vena cava. Pacemaker syndrome results from a complex combination of hemodynamic, neuro-humoral and vascular alterations secondary to the loss of atrioventricular synchrony. Symptoms related to the increase in atrial pressure and venous pressure can, at times, be very debilitating and can include dyspnea, orthopnea, pulsations in the neck and chest, palpitations, thoracic pain.

Conversely, at 40 bpm, the minimum rate is lower than the intrinsic rate of the patient and no pacing is delivered. This allows:

- 1) to reduce energy consumption and prolong the life of the battery,
- 2) to avoid retrograde conduction and
- 3) to effectively pace only upon occurrence of paroxysmal conduction disorder.

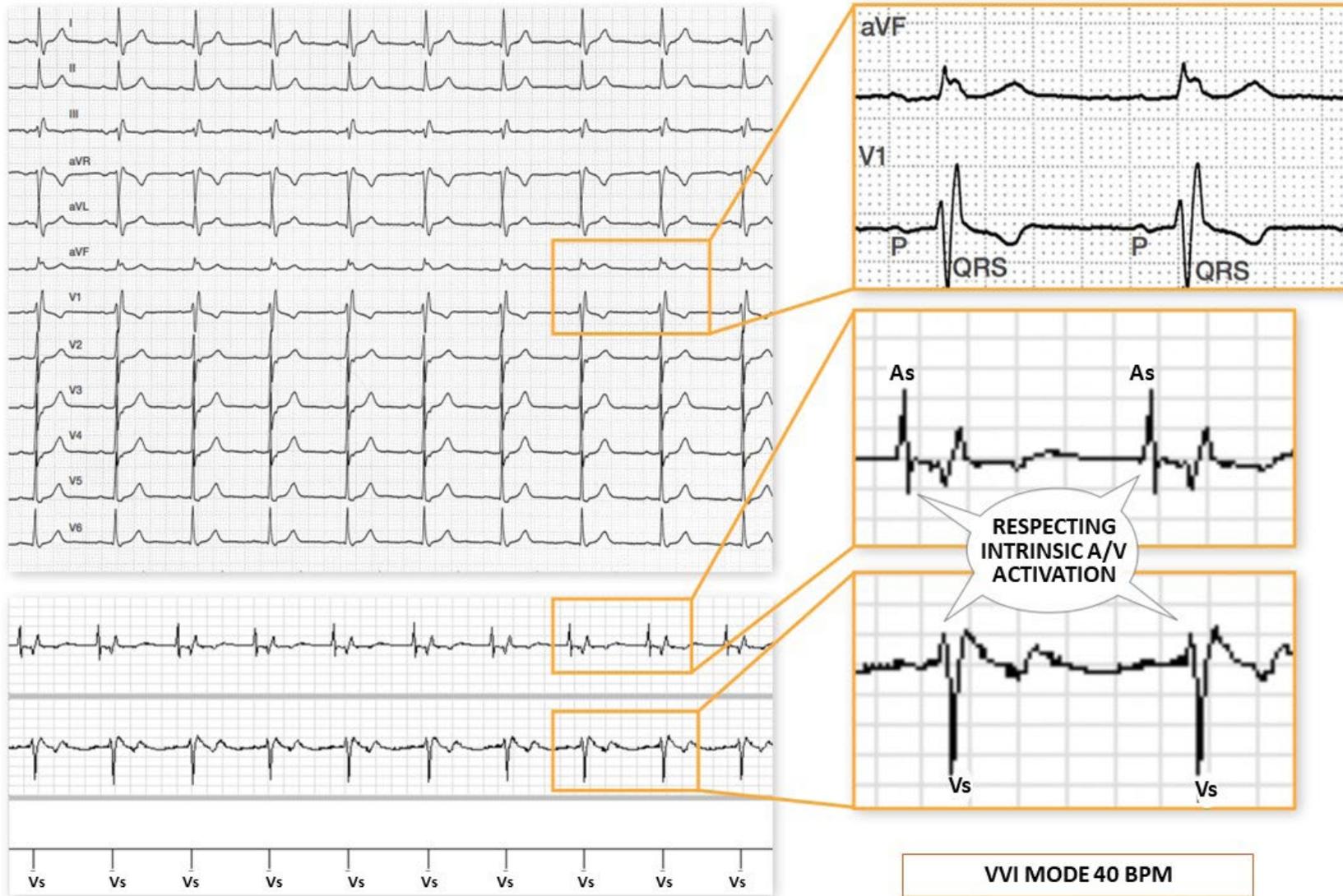
Pacemaker syndrome corresponds to the presence of a repeated sequence with ventricular pacing (pacing artifact and wide QRS) and retrograde atrial conduction (negative P' waves in the inferior leads); atrial contraction may occur against closed A-V valves, which can lead to a variable, if not disabling symptomatology.



Tracing 10: VVI Mode 40 beats/minute

TRACING

VVI mode 40 beats/minute: stand by operation; (observance of, preserved) intrinsic atrioventricular activation; in VVI mode, there are no atrial sensing markers; however, the atrial EGM can reveal the presence of atrial activity preceding the QRS complex;



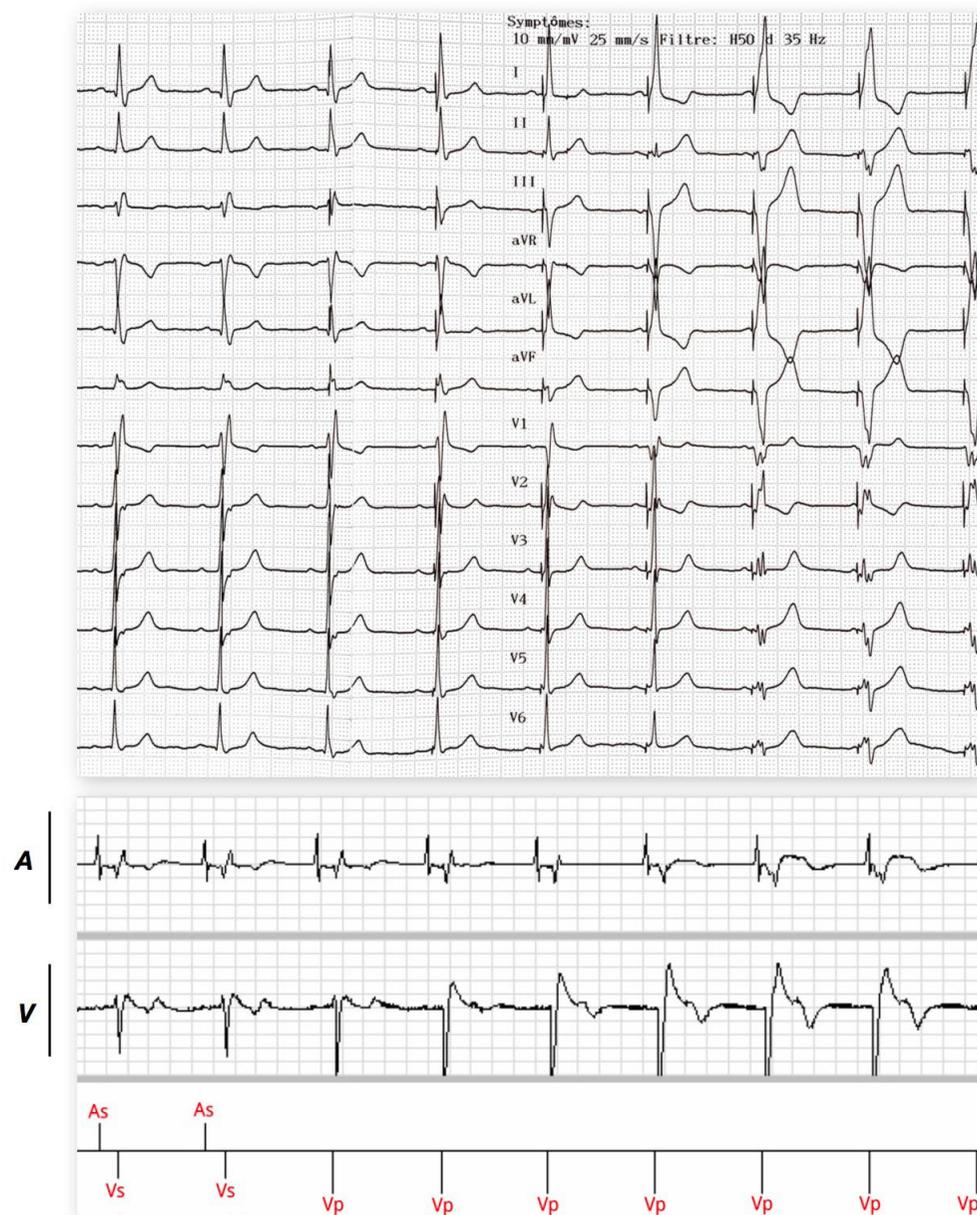
Patient

Same patient as in the first tracing;

Quiz

Which mode is compatible with this tracing?

- A. VVI 60 bpm
- B. VDD 60 bpm
- C. DDI 60 bpm
- D. DDD 60 bpm
- E. VOO 60 bpm



TRACING

VDD mode 60 beats/minute: at the beginning of the tracing, atrial sensing (As) and ventricular sensing (R); rhythm > 60/min; followed by slowing of the sinus rate; in VDD mode, it is not possible to pace the atrium; for MicroPort™ pacemakers, in VDD mode, there is an absolute atrial refractory period preceding ventricular pacing at the programmed minimum rate (in this case, 60/min, VV interval of 1 second); this refractory period is the consequence of virtual atrial pacing with a true AV delay; the P wave is therefore no longer sensed because falling in this atrial refractory period; the P wave gradually falls at the same time than the paced ventricular occurs at the end of the true AV delay; loss of atrioventricular synchrony when the sinus rate slows down with no possibility of atrial pacing; the pacemaker then behaves as if it is programmed in VVI mode;

COMMENTS

When the pacemaker operates in VDD mode, the device senses in the atrium and the ventricle, whereas pacing only occurs in the ventricle. The VDD mode provides synchronized pacing on sensed atrial activity. If there is no atrial event, pacing is VVI at the basic rate. The VDD mode can be programmed on a conventional dual-chamber pacemaker although it may also be obtained in a single-lead VDD dual-chamber device with two floating atrial electrodes for atrial sensing, as well as ventricular bipolar pacing/sensing electrodes. On the other hand, atrial pacing is not possible. This mode is therefore acceptable in the absence of sinus dysfunction; a low basic rate should also be programmed, possibly with rate hysteresis to avoid VVI behavior. Indeed on this tracing, programming at 60 beats/minute is associated with a loss of atrioventricular synchrony. The PMT protection algorithms must be programmed. The fallback algorithm must also be programmed.

The advantages of single-lead VDD systems are:

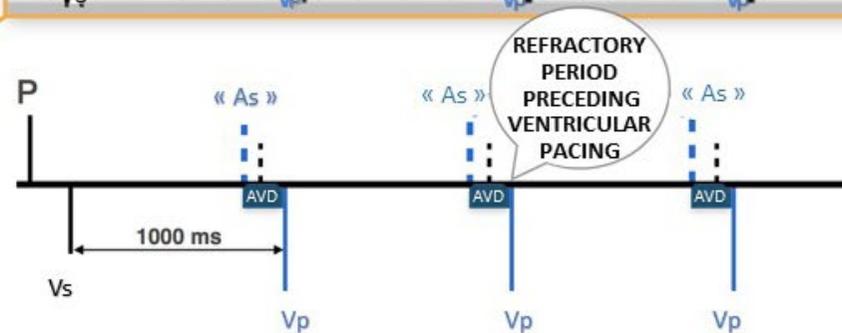
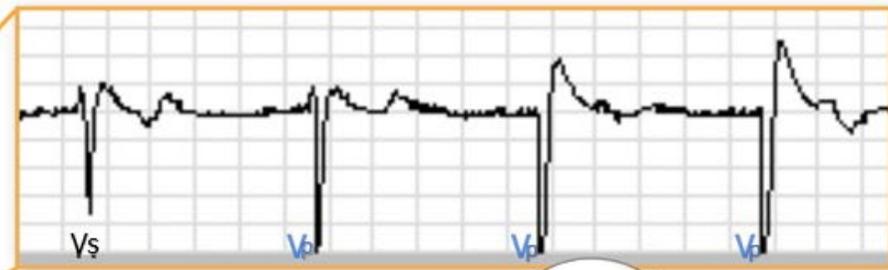
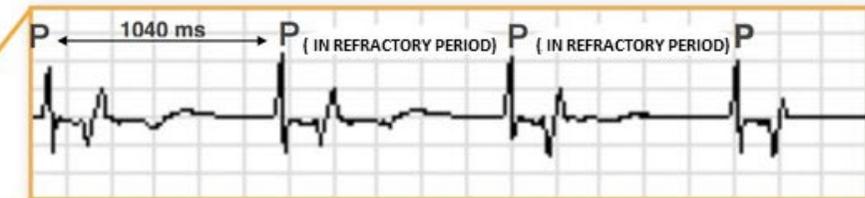
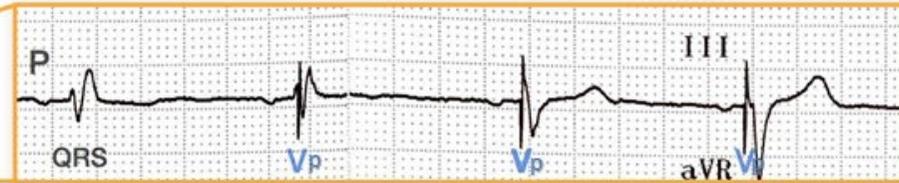
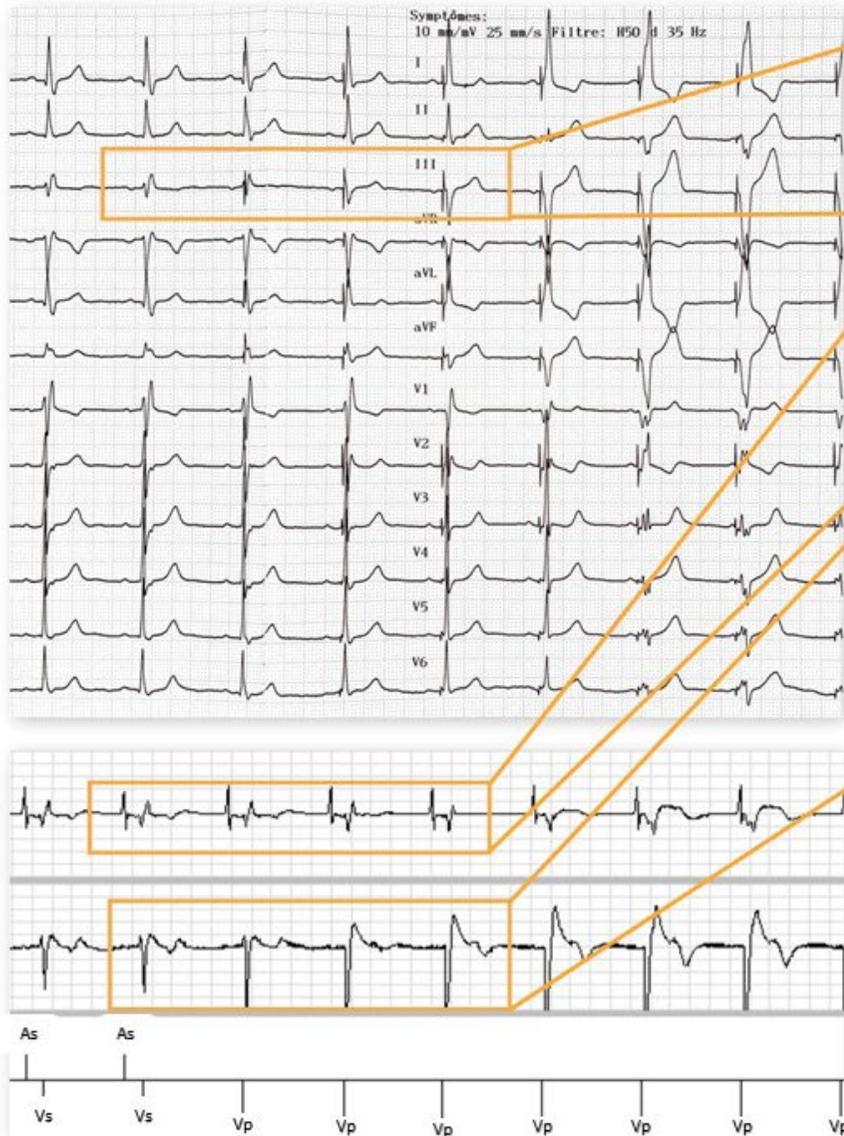
- only one lead is necessary allowing a sometimes shorter implantation procedure while reducing the quantity of required endovascular material
- absence of atrial wall trauma thereby preventing perforation and the development of atrial fibrosis
- in patients without sinus dysfunction, the physiological atrioventricular activation sequence is preserved

The disadvantages of single-lead VDD systems are:

- atrial sensing is sometimes not as effective as that obtains with a separate atrial lead since the atrial dipole can drift away from the wall, especially during deep inspiration and cardiac movements
- similarly, the sensing of atrial arrhythmias is sometimes not as effective for the same reasons, triggering less reliable the device memory
- in the event of loss of paroxysmal atrial sensing on exertion and presence of atrioventricular block, the pacing rate returns to the basic rate with possible sudden drop in rate, possible pacemaker syndrome and risk of PMT
- this mode should be avoided in the presence of sinus dysfunction.

The preferred indication of the VDD mode is therefore complete atrioventricular block with normal sinus function.

The VDD mode is not appropriate for patients with sinus dysfunction, since the device is not allowed to pace the atrium. VDD mode is suitable in patients with complete atrioventricular block, normal sinus function and normal chronotropic function. It is also possible to implant a specific VDD pacing system with a single-ventricular pacing/sensing lead with two floating electrodes for atrial sensing. VDD mode provides synchronized pacing on sensed atrial activity; consequently, the PMT protection algorithms and fallback algorithms must therefore be programmed.



VDD MODE 60 BPM

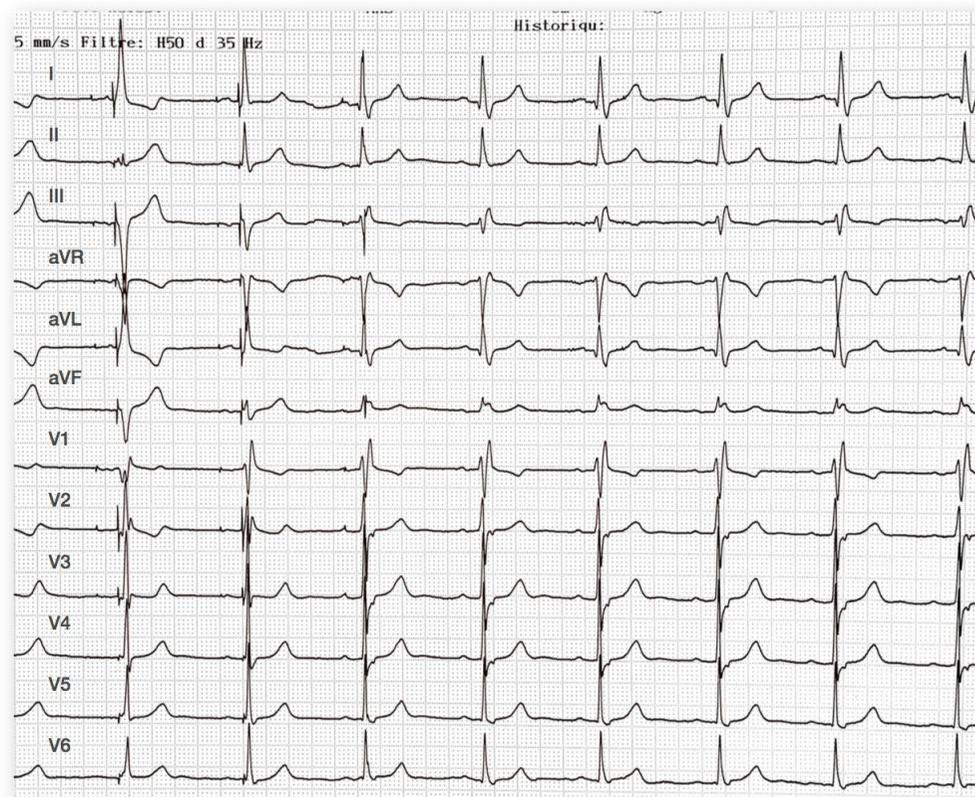
Patient

Same patient as in the previous tracing;

Quiz

Which mode is compatible with this tracing?

- A. VVI 60 bpm
- B. VDD 60 bpm
- C. DDI 60 bpm
- D. DDD 40 bpm
- E. DOO 60 bpm



TRACING

DDI mode 60 beats/minute: at the beginning of the tracing, atrial (Ap) and ventricular (Vp) pacing at the programmed basic rate; thereafter, slight acceleration of the sinus rhythm which becomes faster than the basic rate; as a result of intrinsic atrial activity (As, in the relative refractory period), the pacemaker does not trigger an AV delay, which explains the absence of ventricular pacing and the presence of an intrinsic QRS complex;

COMMENTS

When the pacemaker operates in DDI mode, atrial pacing is performed at the programmed basic rate. After atrial pacing, ventricular pacing occurs at the end of the AV delay if there is no sensed ventricular event during this time. An atrial event sensed outside the refractory periods inhibits atrial pacing and does not trigger an AV delay. Thus, after atrial sensing and in the absence of intrinsic AV conduction, ventricular pacing occurs at the basic rate, disassociated from atrial sensing, as in a VVI pacemaker.

The DDI mode therefore provides dual-chamber sequential AV pacing with atrial and ventricular sensing, but no tracking of the sensed atria. AV synchrony is only provided at the current atrial pacing rate (basic rate, rate-responsive sensor rate, or smoothed rate). If the atrial rate is faster than the atrial pacing rate, there is inhibition of atrial pacing and no AV delay is triggered; when atrial activity is intrinsic, there is no ventricular synchrony.

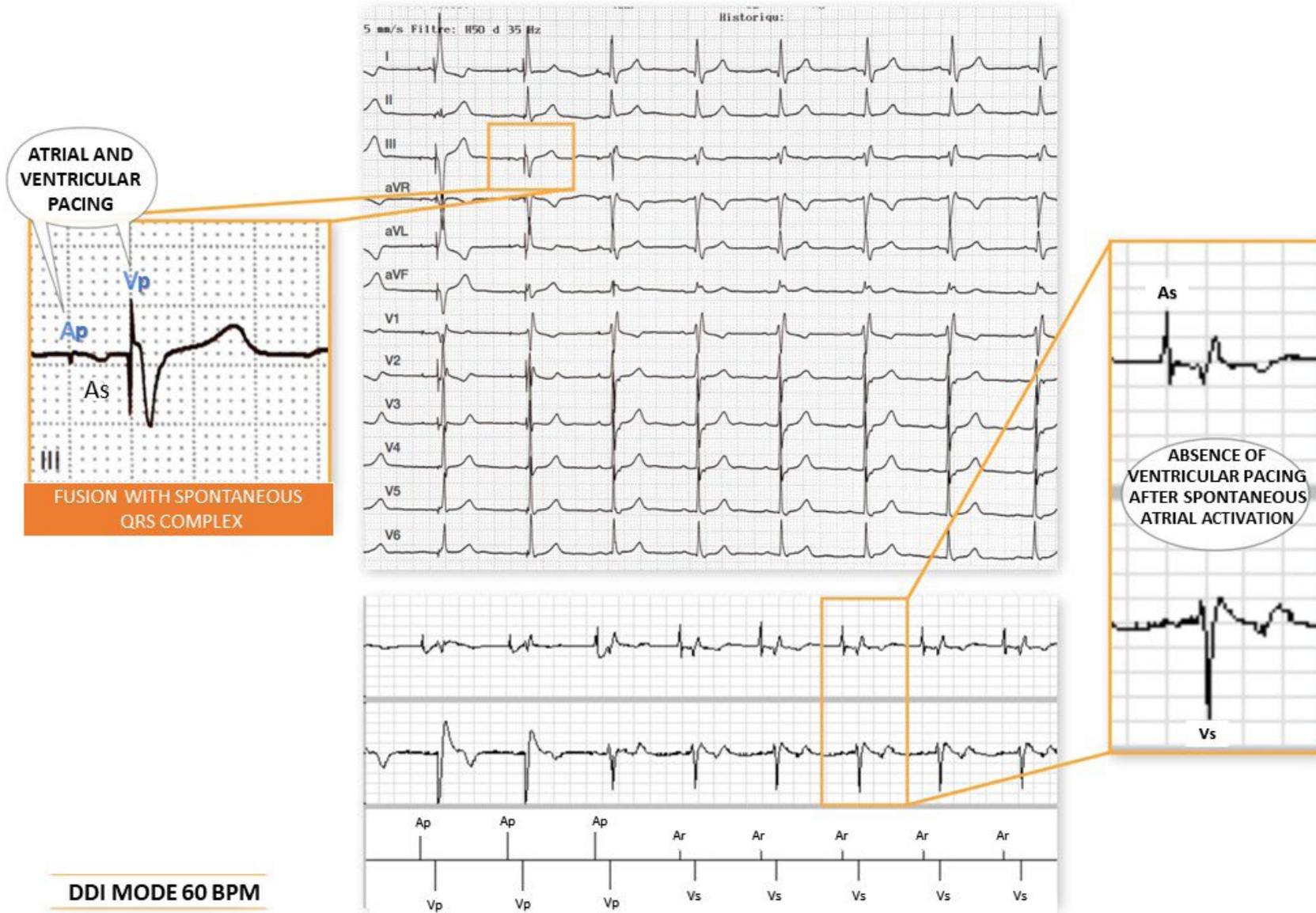
Thus, in the event of complete atrioventricular block, intrinsic atrial events do not synchronize ventricular pacing if intrinsic atrial events are faster than the current atrial pacing rate: operation is therefore equivalent to the VVI mode. This explains the absence of runaway ventricular pacing upon sensing of atrial arrhythmia, hence the

use of DDI as a fallback mode. It is also the selected function when the pacemaker does not correctly sense atrial arrhythmias and therefore does not fallback correctly, with erratic ventricular pacing.

This choice of mode is therefore not appropriate in a patient with atrioventricular block and normal sinus function (no tracking of the sensed atrial events), but is conversely completely acceptable if the patient, even with permanent atrioventricular block, also suffers from sinus dysfunction causing permanent atrial pacing (since atrial pacing synchronizes ventricular pacing). Setting the basic rate is therefore essential. The basic rate should be set high in order to avoid the occurrence of intrinsic atrial activation and should be programmed in combination with rate responsive pacing.

The ideal indication for this mode is a patient with atrioventricular block and atrial disease in conjunction with rapid AF episodes (no risk of runaway) and permanent sinus dysfunction after termination (A-V pacing).

The DDI mode is not adequate in patients with complete atrioventricular block and high intrinsic atrial rate, the intrinsic P waves do not trigger an AV delay. This pacing mode can be programmed in patients with complete atrioventricular block with atrial disease: during sinus rhythm, sinus dysfunction is observed resulting in dual atrioventricular pacing; during an arrhythmia episode, rapid intrinsic atrial activity is not followed by rapid ventricular pacing. This mode is particularly useful when the fallback algorithm is dysfunctional.



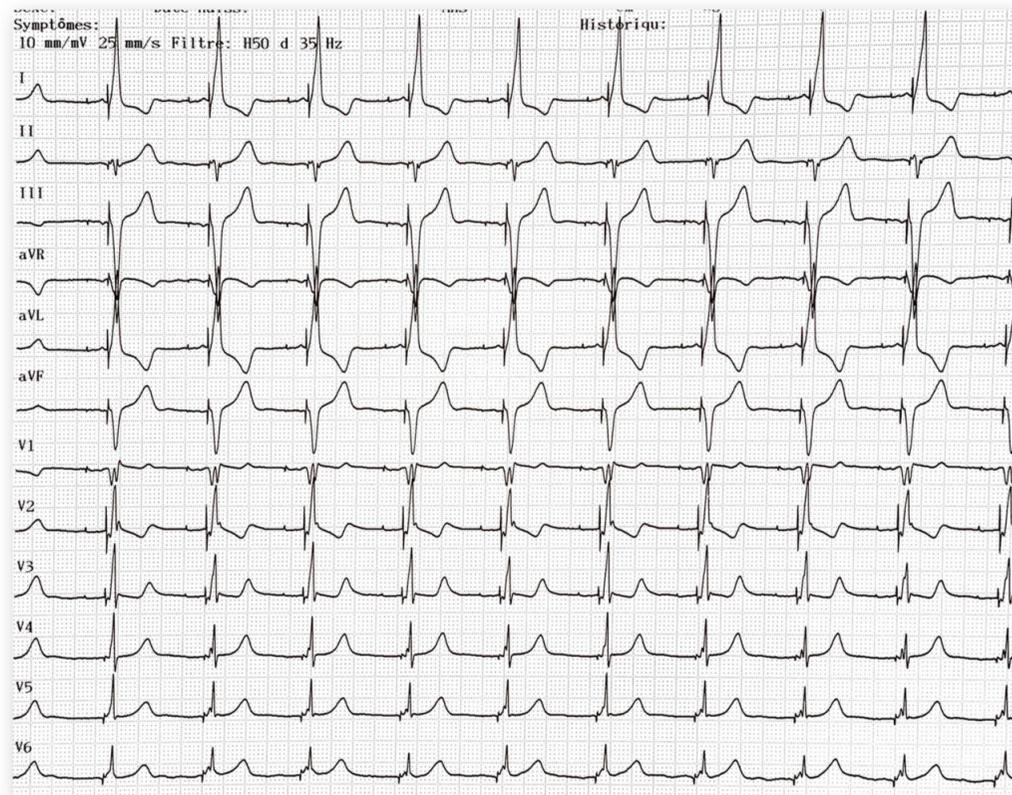
Patient

Same patient as in the previous tracing;

Quiz

Which modes are compatible with this tracing?

- A. VVI 60 bpm
- B. VDD 60 bpm
- C. DDI 60 bpm
- D. DDD 60 bpm
- E. DOO 60 bpm



TRACING

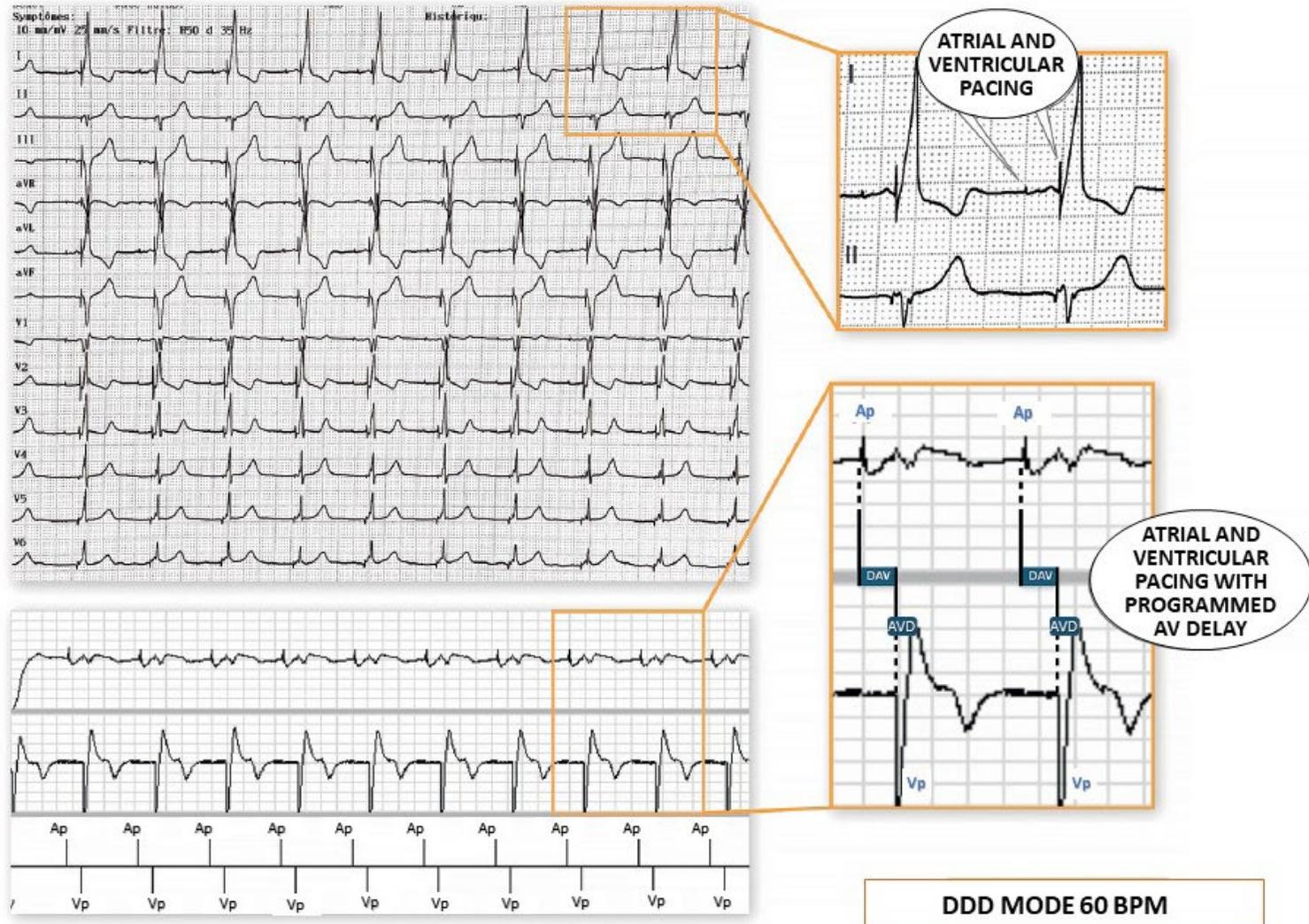
DDD mode 60 beats/minute: atrial pacing and ventricular pacing after a programmable atrioventricular delay;

COMMENTS

The DDD mode is the standard programming mode of dual-chamber pacemakers or resynchronization. It ensures atrioventricular synchrony both at rest and at exercise in response to sensed or paced atrial activity. Indeed, the basic principle of DDD mode is to synchronize ventricular pacing on atrial sensing (triggered operation) or atrial pacing. Intrinsic atrial or ventricular activity sensed outside the refractory period respectively inhibits atrial or ventricular pacing (inhibited operation). This mode therefore preserves atrioventricular synchrony for slow sinus rates up to fast rates (maximum rate limit). Any atrial sensing outside the refractory period between the basic rate and the maximum synchronous rate or atrial pacing results in an AV delay with ventricular pacing in the absence of intrinsic ventricular sensing. AV delays that follow sensed atrial events and paced atrial events can be programmed separately; it is also possible to program shorter AV delays when the rates increase (adaptable AV delay). In DDDR mode, the pacemaker tracks the fastest atrial rate, sinus rate or sensor rate. The maximum synchronous rate and maximal rate response are not independently programmable.

The programming of the DDD mode appears satisfactory in this patient. However, follow-up would probably reveal a percentage of ventricular pacing close 100%. This would correspond to a functioning normal and functioning. Analysis in ODO mode revealed that this patient exhibits proper AV conduction. One of the priorities of pacemaker programming is to avoid unnecessary right ventricular pacing, thereby allowing to reduce battery consumption and prolong the life of the device; more importantly, it decreases right ventricular pacing that is associated with adverse effects in the short, medium and long-term on hemodynamics, ventricular remodeling and occurrence of atrial arrhythmias. Indeed, right ventricular pacing induces an asynchronous interventricular and intraventricular activation and relaxation sequence with delayed activation of the left lateral wall. A high percentage of ventricular pacing in a patient with preserved AV conduction should draw the attention of the physician at the time of device interrogation and should raise the possibility of using specific algorithms promoting intrinsic conduction.

The DDD mode is designed to respond all implanted patients but can be associated with a high percentage of deleterious ventricular pacing in patients with preserved atrioventricular conduction.



Patient

Same patient as in the previous tracing;

Quiz

Which modes are compatible with this tracing?

- A. VVI 60 bpm
- B. VDD 60 bpm
- C. DDI 60 bpm
- D. DDD 60 bpm
- E. AAI SafeR 60 bpm



TRACING

SafeR mode 60 beats/minute: atrial pacing and ventricular sensing;

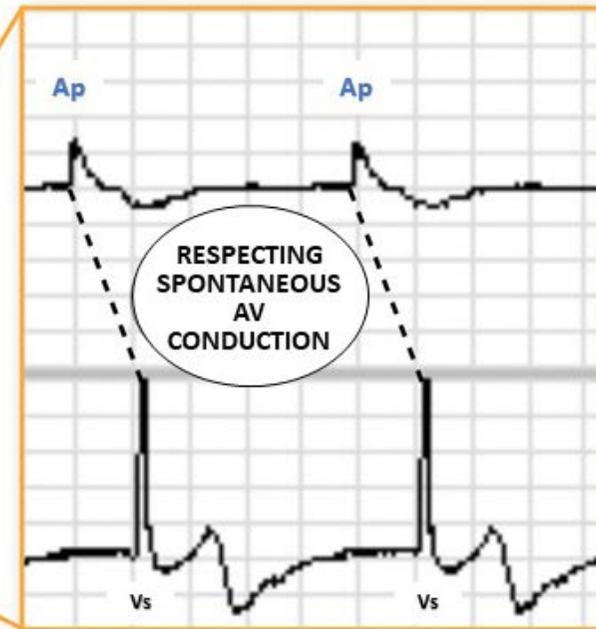
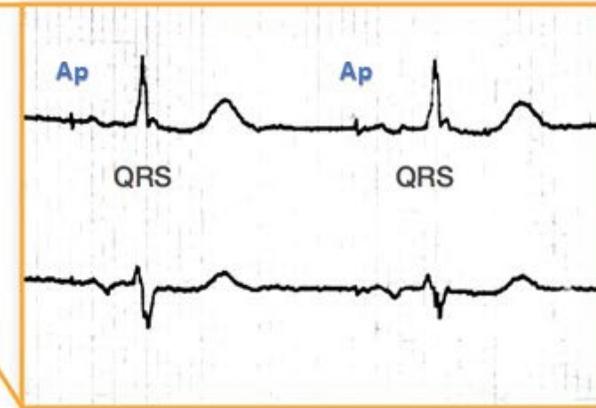
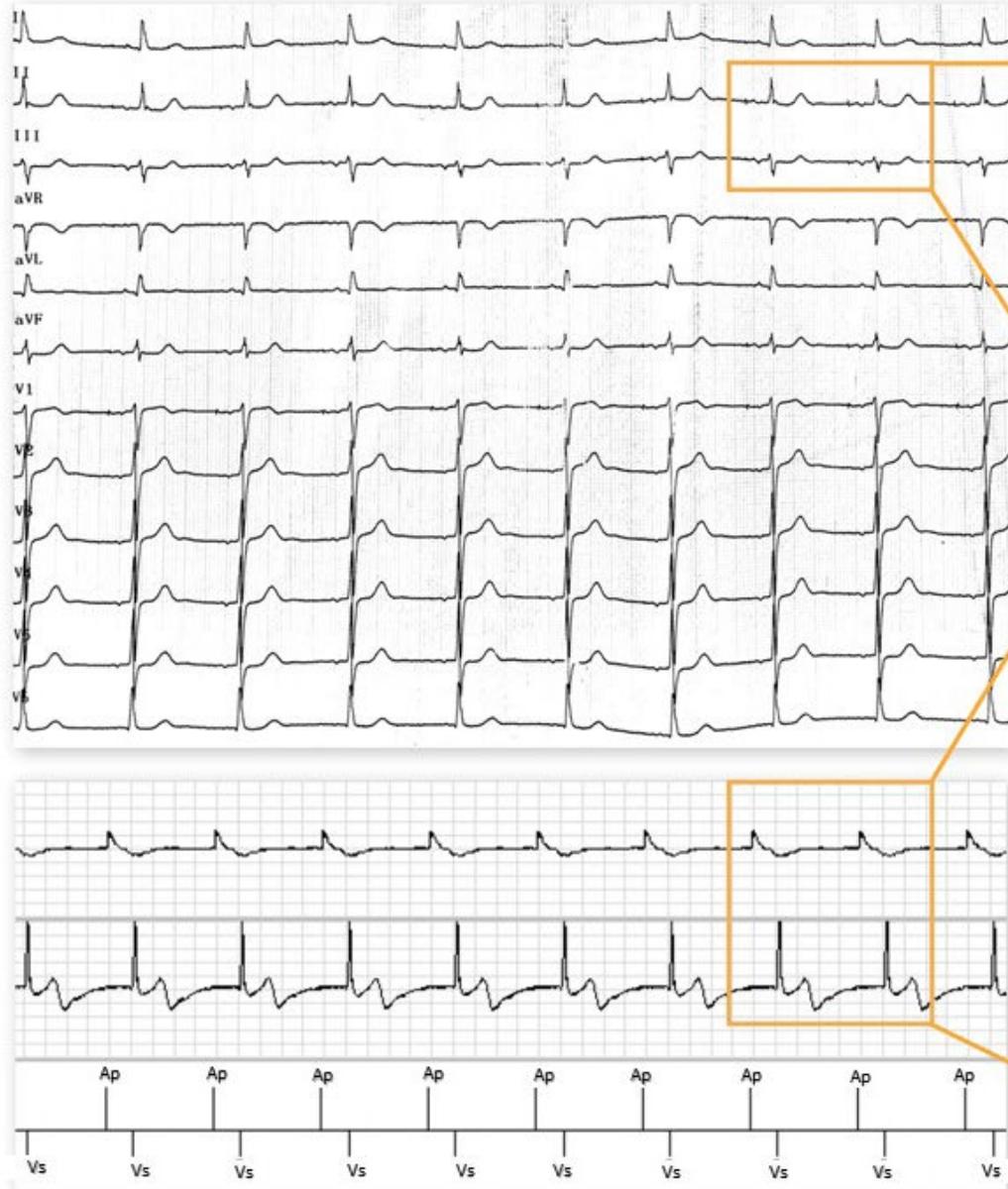
COMMENTS

There is extensive literature demonstrating the deleterious effect of prolonged right ventricular pacing. Likewise, any reduction in the percentage of unnecessary ventricular pacing to reduce battery consumption and to maximize the life of the pacemaker. Different modes have been proposed by manufacturers (SafeR for MicroPort™ pacemakers) to reduce the percentage of ventricular pacing without compromising the safety of the patient upon occurrence of an atrioventricular conduction disorder. The preferred indication of this type of mode is therefore the presence of sinus dysfunction with preserved or paroxysmally-altered atrioventricular conduction.

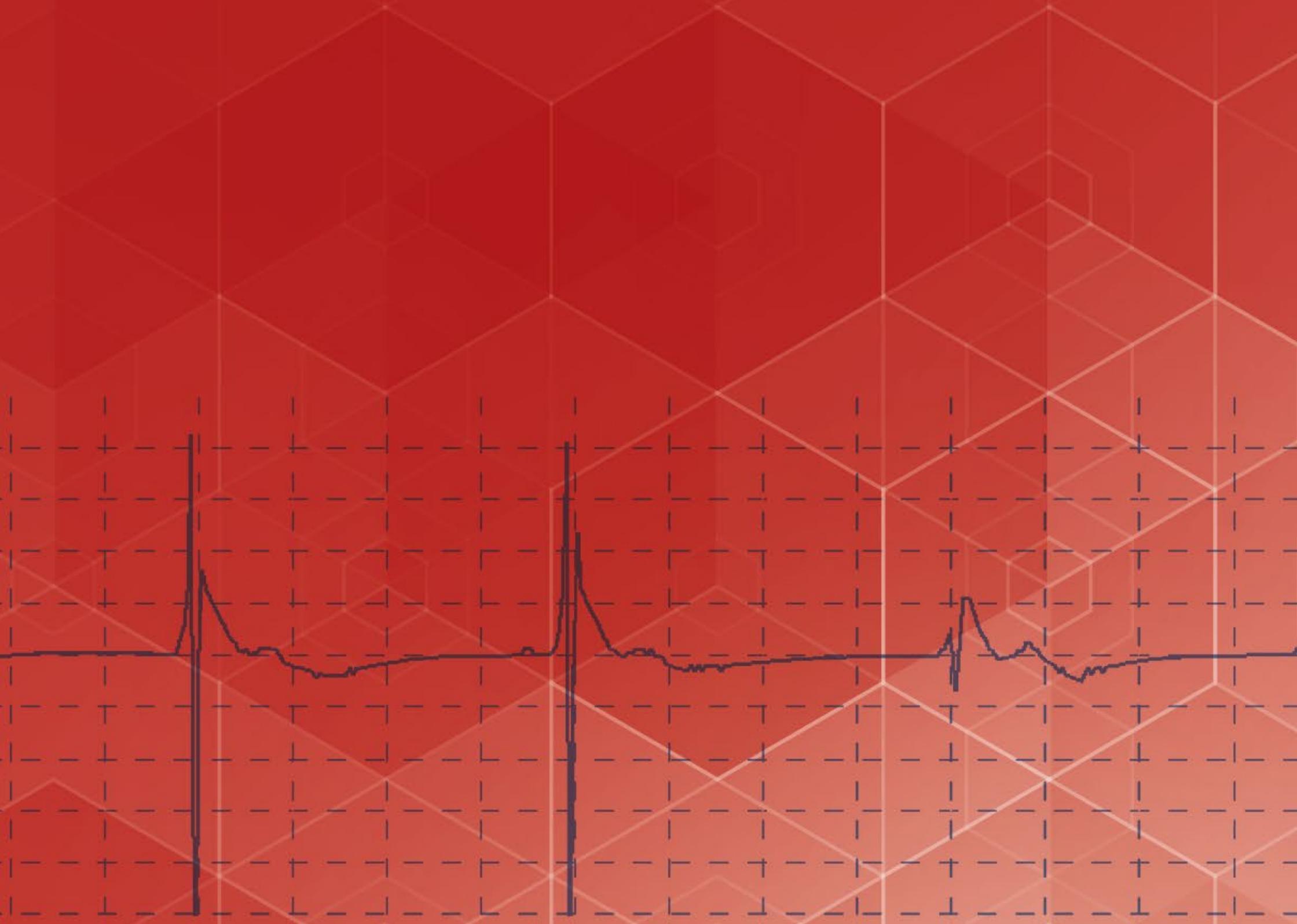
The SafeR mode allows pacing in ADI mode while monitoring atrioventricular conduction. The operation of this algorithm will be explained in detail on the following tracings.

On this tracing, the major advantage of this algorithm is obvious: compared to pacing in DDD mode, programming this mode can significantly reduce the percentage of ventricular pacing. In the long term, this should be beneficial to ventricular remodeling and occurrence of atrial arrhythmia. Analysis of the ventricular pacing percentage is therefore an important component to be monitored in patients with sinus dysfunction, with the goal of minimizing as much as possible the occurrence of any unnecessary ventricular pacing.

Each manufacturer has developed a specific pacing mode to decrease the percentage of unnecessary right ventricular pacing in non-pacemaker-dependent patients. The particular functioning of these different modes must be known by the physician in order to be able to interpret each tracing.



SAFER MODE 60 BPM



Pacemaker - **chapter 2**

SafeR Mode



Patient

65-year-old man with a MicroPort™ Reply DR pacemaker for sinus dysfunction with moderately increased PR interval at implantation (220 ms); programming: SafeR-R mode, basic rate 55 bpm, maximum rate 130 bpm, AVB I switch rest+exercise, long PR max 350 ms, long PR min 250 ms, max pause 3 s; recording of AVB I switch episodes in pacemaker memory;

Quiz

What is(are) the correct answer(s) regarding the SafeR mode?

- A. the pacemaker switches after 6 consecutive cycles with a PR interval longer than the programmed value
- B. the pacemaker switches after 2 cycles with a PR interval longer than a fixed value of 450 ms
- C. the value programmed for the AVB I criterion corresponds to the PR interval on a sensed P wave
- D. an V_s interval is considered long if longer than the programmed PR value + 100 ms
- E. an V_s interval is considered long if longer than the programmed PR value + 50 ms



Tracing 15: First-degree AV block (AVB I) criterion

Correct Answers : A, C, D

TRACING

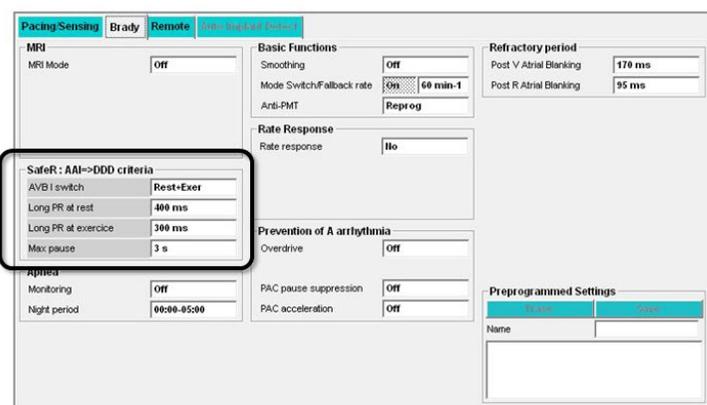
Atrial pacing (Ap) and ventricular sensing (Vs); at the beginning of the tracing, PR intervals oscillates between 367 and 406 ms and is therefore lower than the programmed value of the long PR at rest (350 + 100 ms); prolongation of the PR interval exceeding the programmed value of the long PR at rest (484 then 515 ms) over 6 consecutive cycles; switch to DDD mode (vertical line) and ventricular pacing (AV cycles) with programmed AV delay;

COMMENTS

On a surface electrocardiogram, the PR interval corresponds to the delay between the depolarization of the first atrial cell and the depolarization of the first ventricular cell. The PR interval can be divided into 2: the P wave, whose duration is the depolarization time of the 2 atria, and the PR segment, measured between the end of the P wave and the beginning of the R wave, which represents the conduction delay in the atrioventricular node and the His-Purkinje network. The PR segment is most often isoelectric, the signals generated by the traversed structures not being of sufficient amplitude to be detected on the surface electrocardiogram.

The first-degree atrioventricular block (AV block) corresponds to a simple prolongation of the PR interval which exceeds the physiological values; there is an equal number of P waves and QRS complexes and a fixed, constant PR space, exceeding 200 ms in adults; if sinus function is normal, there is no bradycardia (ventricles at the same rate as the atria). The term AV block is therefore not appropriate since, technically-speaking, it is not a block (interruption of conduction) but rather a slowing of conduction.

The SafeR mode was designed to provide ADI pacing with continuous monitoring of atrioventricular conduction and switch to DDD mode when the pacemaker detects impaired conduction. There are 4 switch criteria corresponding to the different degrees of atrioventricular block (AVB I, AVB II, AVB III, pause). A certain number of parameters are programmable, 3 of them pertain to the AVB I criterion such as to allow a physiological response in patients exhibiting a paroxysmal prolongation of the PR interval. The maximum and minimum PR values are programmable as well as the possibility of programming this parameter in response to exercise only (switching possible only on exertion) or at rest + exercise (the switch occurs at rest and in exercise). The pacemaker switches to the DDD mode when the PR interval exceeds the programmed limit value for 6 consecutive cycles (6 is non-programmable value). The programmed value corresponds to the limit value on an intrinsic atrial activation (As). For a paced atrium (Ap), the limit value corresponds to the sensed value + 100 ms (non programmable).



SafeR: AAI->DDD criteria		
AVBI switch	Rest+Exer	Exercise
Long PR at rest	400 ms	Rest+Exer
Long PR at exercise	300 ms	
Max pause	3 s	

SafeR: AAI->DDD criteria		
AVBI switch	Rest+Exer	
Long PR at rest	400 ms	300 ms
Long PR at exercise	300 ms	350 ms
Max pause	3 s	400 ms
Apnea		
Monitoring	Off	450 ms
Night period	00:00-05:00	500 ms

What value should be programmed in terms of maximum PR duration? From what length of time should a PR interval be considered too long and should ventricular pacing be preferred? The answer to these questions is complex and must integrate various parameters: presence of symptoms, left ventricular ejection fraction, duration of the QRS complex. In an asymptomatic patient, with normal ejection fraction and narrow QRS, it may be desirable to favor the intrinsic condition so as to avoid asynchronous activation induced by right ventricular pacing as well as increased energy consumption despite suboptimal filling in relation to the long PR. The parameter can then be programmed at exercise only or at both on rest + exercise with relatively long PR values (long max PR at 350-400 ms and long min PR at 250 ms).

In SafeR mode, the pacemaker switches when the PR interval exceeds a programmable value over 6 consecutive cycles; the limit value on atrial pacing is 100 ms longer than on sensed atrial event.



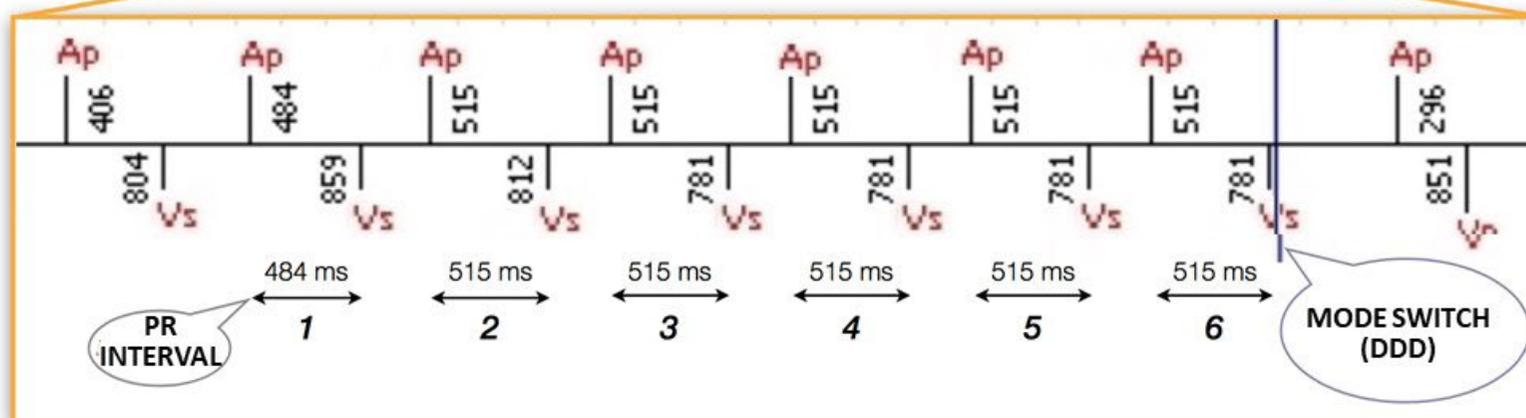
Settings:

SafeR-R 55 bpm, AVB I rest and exercise,
long PR max 350 ms, long PR min 250ms

- Ap-Vs long max 450ms
- Ap-Vs long min 350 ms

AVB I criterion

6 consecutive cycles with As/Ap – Vs interval
longer than programmed value



Patient

68-year-old man with a MicroPort™ Kora 100 DR dual-chamber pacemaker for sinus dysfunction; programming: SafeR-R mode, base rate 60 bpm, maximum rate 130 bpm, AVB I switch rest+exercise, long PR max 350 ms, long PR min 250 ms, max pause 3 s; recording of episodes AVB I switch episodes during (exertion, exercise) in pacemaker memory;

Quiz

What is(are) the correct answer(s) regarding the SafeR mode?

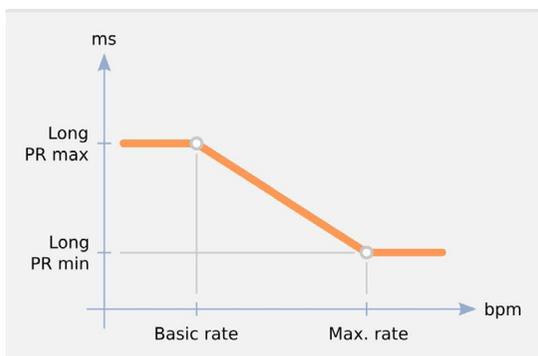
- A. the AVB I criterion can be programmed to rest + exercise
- B. the AVB I criterion can be programmed to rest only
- C. the AVB I criterion can be programmed to exercise only
- D. the rate defining the beginning of exercise is programmable
- E. the rate defining the end of exercise is programmable

TRACING

Rate responsive (>120/mn) atrial pacing (Ap) and ventricular (Vs) sensing; switch to DDD mode after 6 consecutive AR intervals exceeding the programmed value of the long PR;

COMMENTS

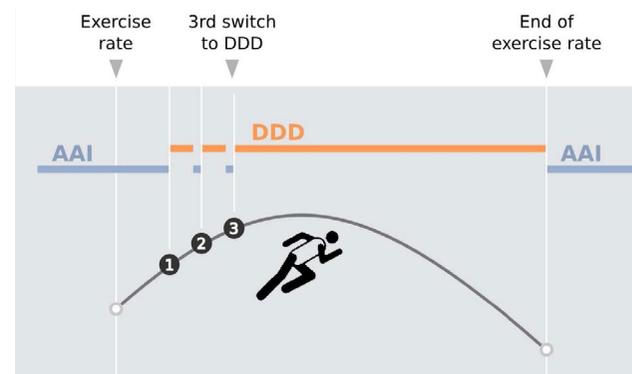
The presence of a very long PR interval may be associated with the occurrence of symptoms, if the response to exercise is not physiological. Indeed, in the absence of reduction of the PR interval concomitant with the increase in exercise rate, the atrial systole following atrial depolarization occurs too early during ventricular diastole. Atrial systole may even occur at the end of ventricular systole resulting in a loss of active atrial contribution to cardiac ejection, a shortening of left ventricular filling time, diastolic mitral regurgitation and, in most cases, atrial contraction against closed AV valves. This can be more or less marked symptomatic (exertional dyspnea, retrograde flow sensation in the jugular veins, palpitations, malaise) similar to that observed in paced patients in VVI mode with retrograde conduction (pacemaker syndrome). A certain number of uncontrolled studies suggest that pacemaker implantation can reduce symptoms and improve functional status in this setting. In the latest European recommendations, there is a hemodynamic indication (Class IIA) for pacemaker implantation. Permanent pacemaker implantation should be considered for patients with persistent symptoms similar to those of pacemaker syndrome and clearly attributable to first-degree AVB (PR >0.3 s).



As explained previously, it is possible to program the AVB I criterion at rest + exercise or at exercise only.

When the basic rate is programmed at 70 bpm or less, rest corresponds to the zone between the basic rate and 100 bpm (non-programmable) during rate acceleration. Exercise corresponds to the zone between 100 bpm and the programmed maximum rate. During rate decrease, exercise corresponds to the zone between the maximum rate and 90 bpm.

When the basic rate is programmed to greater than 70 bpm, rest corresponds to the zone between minimum rate and minimum rate + 30 bpm during acceleration. Exercise corresponds to the zone between minimum rate + 30 bpm and the programmed maximum rate. During rate decrease, exercise corresponds to the zone between maximum rate and minimum rate + 20 bpm.

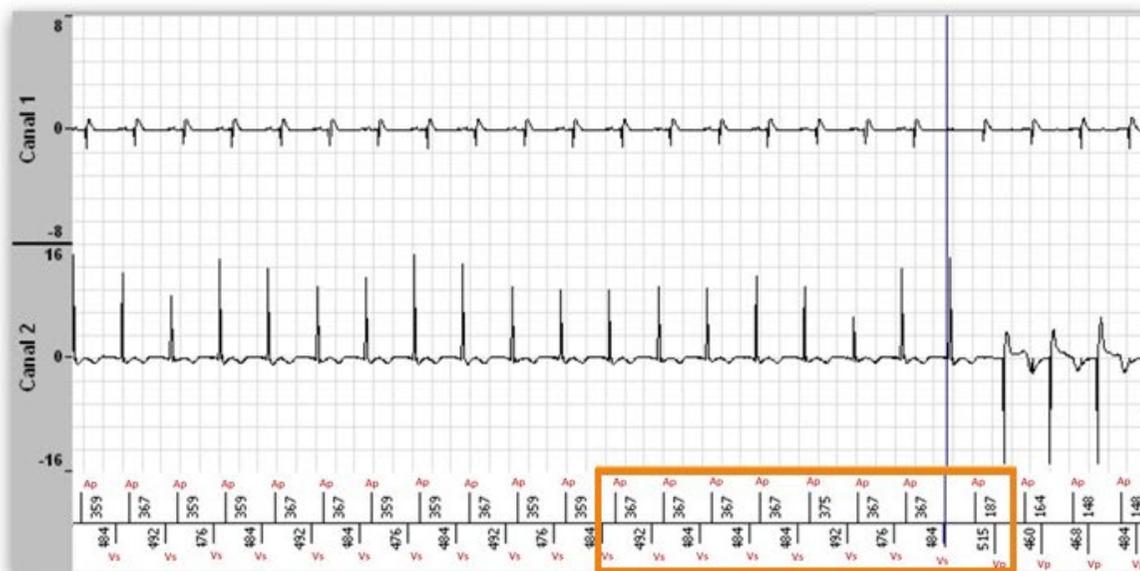


For this patient (basic rate at 55 bpm), if the parameter is programmed to exercise only, switch on a long PR only occurs for a rate > 100 bpm during rate increase then > 90 bpm during rate decrease.

When the parameter is programmed to rest + exercise, the limit value defining a long PR varies linearly between the PR maximum value at the basic rate and the PR minimum value at the maximum rate.

For a same exercise, when the device diagnoses 3 ADI mode switches, the device remains in DDD mode until the end of the exercise (no switch back to ADI mode until the end of this exercise defined by a rate < 90 bpm).

When the PR interval is extremely prolonged, the physiological activation/contraction sequence between atria and ventricles is no longer preserved leading to contraction of the atria while the AV valves are closed, this can be associated to symptoms. In this setting, the SafeR algorithm allows to switch to DDD mode in order to restore a physiological atrioventricular activation sequence. The nominal value of 250 ms for the minimum PR is applied at the maximum rate, and therefore to the maximum capacities of the patient, appears as a good compromise to limit the occurrence of symptoms while avoiding iterative switching.

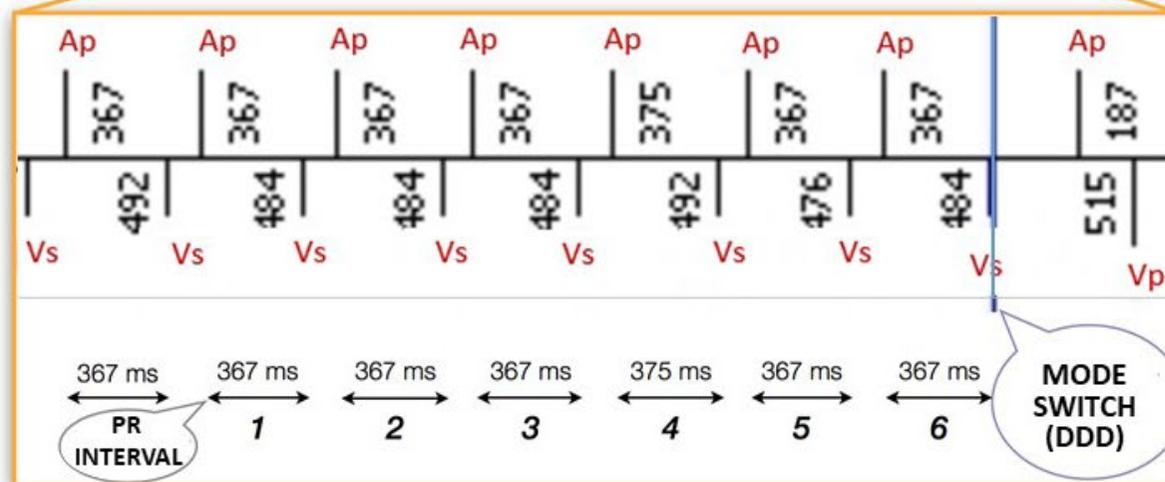


Programming:

SafeR-R 60 Bpm, AVB 1 rest and exercise, Long PR max 350 ms, Long PR min 250 ms.

- ApVs long max 450 ms
- ApVs long min 350ms

AVB 1 criterion
Linear threshold depending
on heart rate



Patient

62-year-old woman with a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction and paroxysmal AV block; programming: SafeR-R mode, basic rate 60 bpm, maximum rate 130 bpm;

Quiz

What is(are) the correct answer(s) regarding the SafeR mode?

- A. the AVB II criterion can be programmed to exercise only
- B. the AVB II criterion can be programmed to rest only
- C. the pacemaker switches if 2 in 6 non-consecutive atrial events are blocked
- D. the pacemaker switches if 2 in 4 non-consecutive atrial events are blocked
- E. the pacemaker switches if 3 in 12 non-consecutive atrial events are blocked



TRACING

At the beginning of the tracing, atrial pacing with spontaneous atrioventricular conduction; second-degree atrioventricular block with alternating conducted atrial pacing and blocked atrial pacing (2:1 block pattern); after 3 non-consecutive blocked atrial complexes, the AVB II criterion is fulfilled (non-programmable parameter, 3 in 12 blocked atrial activities); switch to DDD mode (vertical line);

COMMENTS

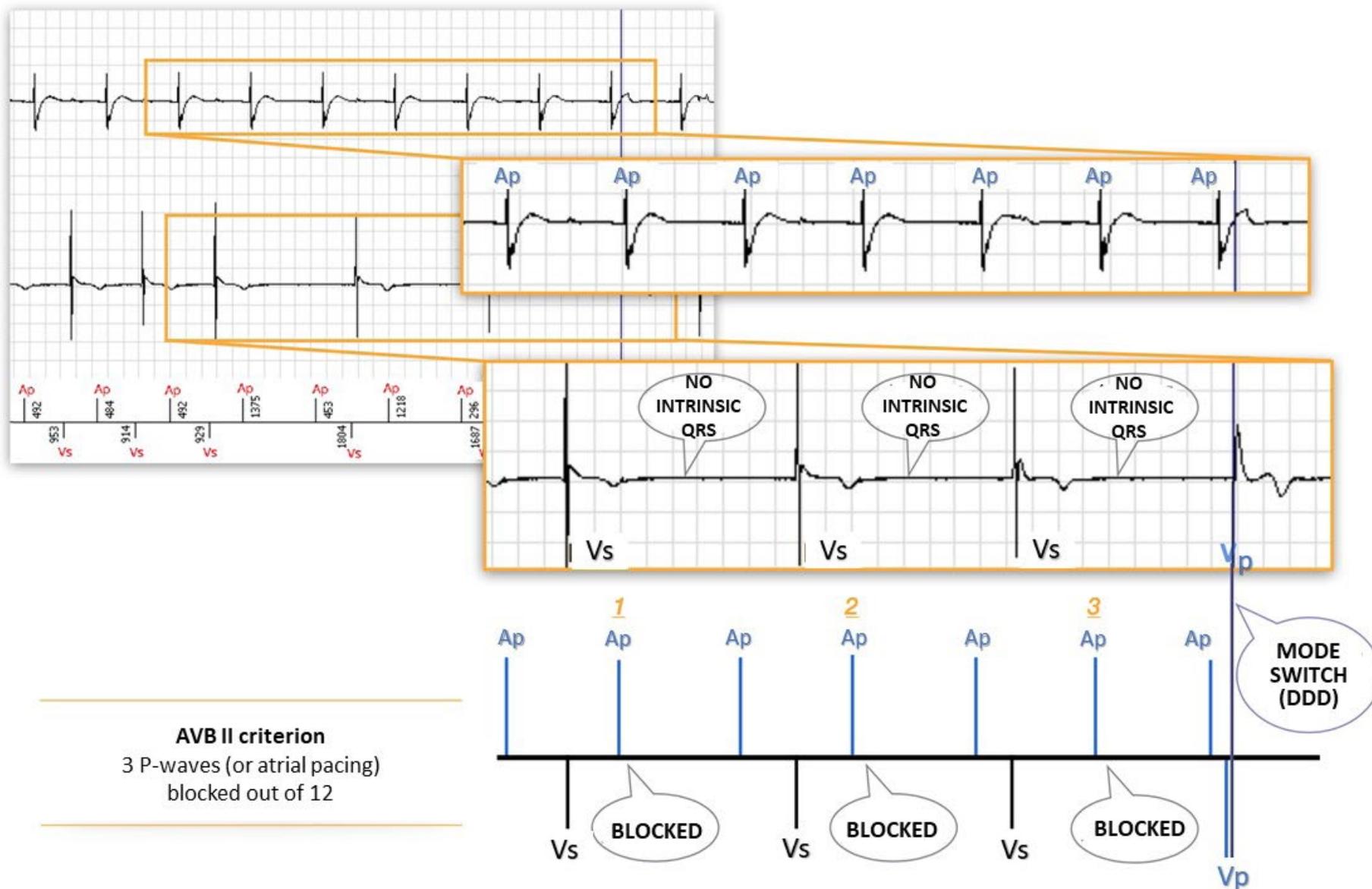
The second degree atrioventricular block type 1 (Mobitz 1) is defined by the intermittent presence of a blocked P wave with a variable PR interval. The Luciani-Wenckebach second-degree AV block corresponds to a gradual prolongation of the PR interval until the occurrence of a blocked P wave; after the pause, the next P wave is conducted with a PR interval returning to the baseline value and then the same sequence is reproduced (Luciani-Wenckebach periods). These periods can last more or less between 2 and 10 conducted P waves one blocked P-wave along. The second-degree AV block type 1 primarily corresponds to a conduction disorder located at the level of the atrioventricular node and to an exaggeration of the decremental conduction. This location explains the predominantly normal morphology of the QRS complexes. During an electrophysiological study, a nodal slowdown results in a progressive prolongation of the AH interval, with the normal HV interval and the blocked P wave not followed by a Hisian potential. Indications for implantation in the events of a second-degree AV block type 1 are controversial. The relationship between conduction disorder and the onset of symptoms is difficult to establish, especially when symptoms are low and non-specific. There is a Class IIA indication in European recommendations when a second-degree AV block type I is responsible for symptoms or when the location of the conduction disorder is intra- or infra-Hisian (major risk of progression to complete atrioventricular block) upon electrophysiological study.

The second-degree atrioventricular block type 2 (Mobitz 2) is much rare than type 1; blocked P waves not followed by QRS occur unexpectedly, without prior prolongation of

the PR space. The electrocardiogram thus shows an intermittent blocking of the P wave; the recurrence of blocked P waves can be regular, although most often are irregular; the number of blocked P waves is generally increased by maneuvers that increase the heart rate (exercise, atropine) and vice versa for the maneuvers that decrease the heart rate. The PR interval of the conducted complexes remains constant. Ventricular pauses are twice the normal duration of the RR interval. Second-degree AV block type 2 is mostly the result of an irreversible degenerative anatomical lesion. The recording of the potentials of the bundle of His reveals that the origin of the intermittent conductance blockage is usually located in the distal part of the bundle of His or in one of the three branches, the other two already being blocked (intra- or infra-Hisian block). This explains the constancy of the PR interval before and after the blocked P wave, with conduction occurring according to an all-or-nothing principle. This type of block is an indisputable indication for pacemaker implantation. Indeed, the progression towards third-degree AV block is common; furthermore, because of the location of the block, potential escape (routes) are located inferiorly and are often slow and unstable, thereby increasing the risk of syncope or sudden death.

In the SafeR algorithm, the AVB II criterion is not programmable. The pacemaker switches to DDD mode when 3 in 12 atrial events (sensed outside of the relative refractory period or paced) are blocked. The ratio between blocked P waves and conducted P waves leading to mode switch cannot be changed.

The second-degree AV block type 1 with Luciani-Wenckebach sequences corresponds to a progressive prolongation of the PR interval until the occurrence of a blocked P wave. The second-degree AV block type 2 (Mobitz 2) corresponds to the occurrence of a blocked P wave without prior modification of the PR interval (PR constant before and after the pause). When the SafeR mode is programmed, the pacemaker switches to DDD mode when 3 in 12 atrial activities are blocked (non-programmable ratio):
AVB II criterion.



Patient

62-year-old woman with a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction and paroxysmal AV block; programming: SafeR-R mode, basic rate 60 bpm, maximum rate 130 bpm;

Quiz

What is(are) the correct answer(s) regarding the SafeR mode?

- A. the pacemaker switches when 2 consecutive atrial events are blocked
- B. the pacemaker switches when 2 consecutive atrial pauses are blocked
- C. the number of blocked atrial events defining the AVB III criterion is programmable
- D. the AVB III and pause criteria can be fulfilled on the same tracing
- E. the AVB III criterion may be deprogrammed while maintaining the AVB II and AVB I criteria



TRACING

At the beginning of the tracing, atrial pacing with intrinsic atrioventricular conduction; 2 consecutive blocked atrial complexes; the AVB III criterion is fulfilled (non-programmable parameter, 2 consecutive blocked atrial activities); switch to DDD mode (vertical line);

COMMENTS

The diagnosis of complete atrioventricular block is defined by the complete interruption of atrioventricular conduction and is based on the presence of atrioventricular dissociation, the atria and ventricles being under the control of independent pacemakers, with the ventricular rate slower than the atrial rate. There is no relationship between P waves and QRS complexes, while the PR intervals are variable without repetitive sequence.

An escape rate in a patient with third-degree AV block is generally regular, with the electrocardiogram showing atrioventricular dissociation and the presence of regular ventricular bradycardia with monomorphic QRS complexes. At times, the escape can be

unstable or absent, its activity slowing down or interrupting abruptly, which can cause the occurrence of serious symptoms of varying degrees depending on the duration of the pause, including leading to sudden death.

In the SafeR algorithm, the AVB III criterion is not programmable. This criterion is not based on the presence of atrioventricular dissociation (slower and dissociated ventricular rate compared to the atrial rhythm, with regular ventricular escape) but rather on the presence of consecutive blocked atrial events.

Diagnosis

- The device switches to DDD mainly on AVB II criteria.
- 2 % of DDD switching occurs after sensing a signal within the committed period. The R wave sensed in the committed period can be due to an A sensing error or a long PR.

Curves and histograms

- Occurrence of AVB
- AVB History
- AV delay value distribution

AVB episode table

	Day distr.		Night distr.	Total
	Day in exer	Day at rest		
Pause	-	5 (45%)	6 (55%)	11
AVB I	13 (100%)	-	-	13
AVB II	523 (6%)	5924 (62%)	3039 (32%)	9486
AVB III	-	5 (56%)	4 (44%)	9
AVB Episodes	11 (0%)	2965 (63%)	1711 (37%)	4687

Total number of switches during the follow up: 9519
One AVB episode can lead to several switches.

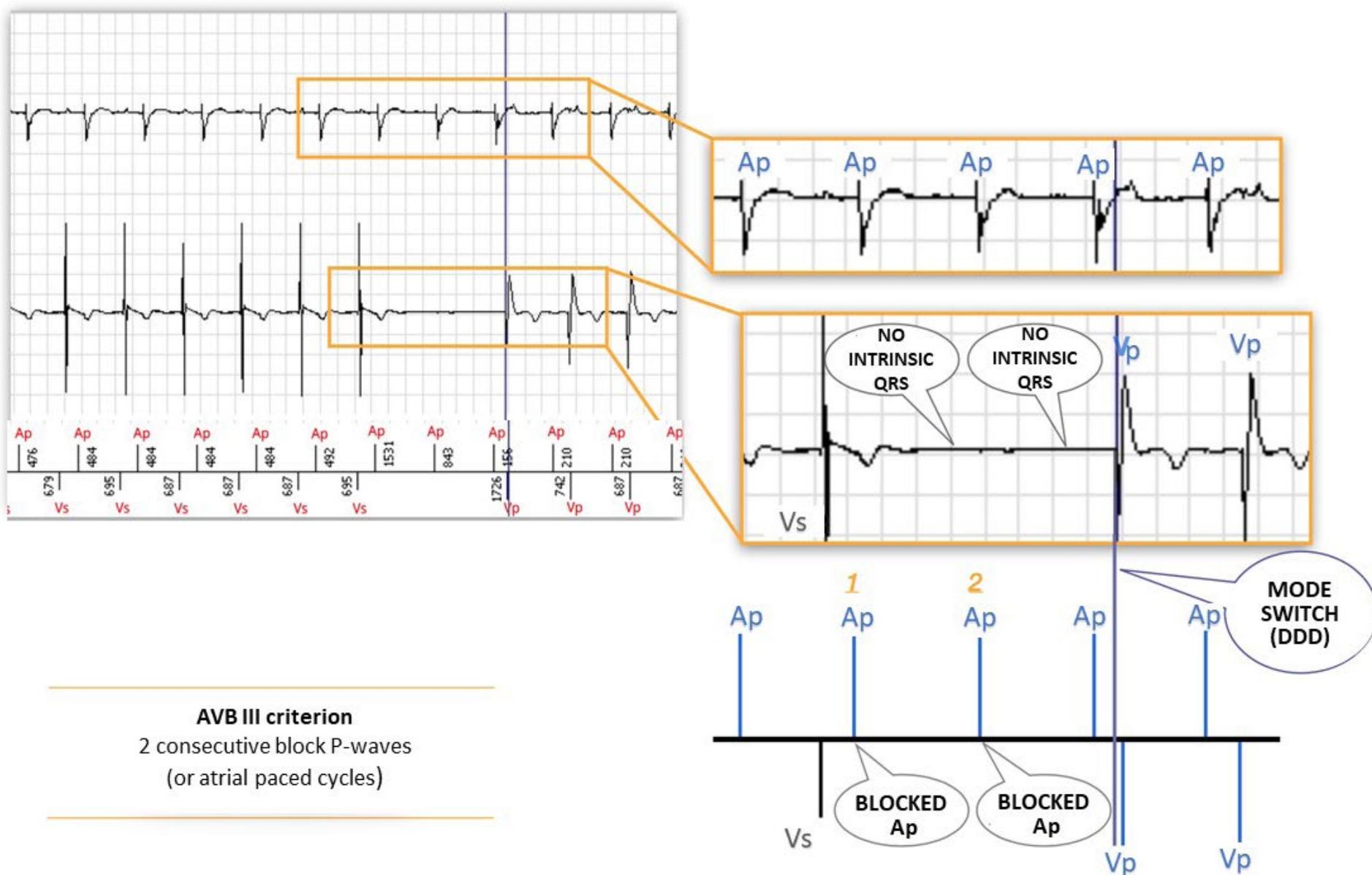
Details

SafeR MODE	
AAI Mode	78%
P waves blocked	489
Atrial stimulations blocked (with sensor)	99086 (67%)
Mode Switch AAI=>DDD	9727
AAI=>DDD on Pause	11
AAI=>DDD on III AVB	9
AAI=>DDD on II AVB	9486
AAI=>DDD on I AVB	13
AAI=>DDD for Safety	208
Occurrence of AVB	4687
Safety AVR	114

The pacemaker therefore switches to the DDD mode when 2 consecutive atrial activities (sensed outside the refractory period or paced) are blocked. The number of consecutive blocked atrial activities leading to a mode switch cannot be changed.

Interrogation of the device memory allows to see in detail the number of mode switches and the distribution between switches according to AVB I, AVB II, AVB III or Pause criteria.

The diagnosis of complete AV block is defined by the complete interruption of atrioventricular conduction following a conduction block located at the (AV) junction, the bundle of His or bundle branches. The lower the location of the atrioventricular block (distal conduction disorder), the greater the risk of slow, weak and intermittent escape rhythm, which explains the increased risk of syncope or sudden death. When the SafeR mode is programmed, the pacemaker switches to DDD mode when 2 consecutive atrial activities are blocked: AVB III criterion.



AVB III criterion
 2 consecutive block P-waves
 (or atrial paced cycles)

Patient

62-year-old woman with a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction and paroxysmal AV block; programming: SafeR-R mode, basic rate 60 bpm, maximum rate 130 bpm;

Quiz

What is(are) the correct answer(s) regarding the SafeR mode?

- A. the pause criterion is not programmable and is fixed at 2 s
- B. the pause criterion is not programmable and is fixed at 3 s
- C. the pause criterion is programmable at 2 or 3 s
- D. the pause criterion is programmable at 2, 3 or 4 s
- E. the pause criterion is programmable at 2, 3, 4 or 5 s



TRACING

At the beginning of the tracing, atrial pacing with intrinsic atrioventricular conduction; blocked atrial pacing; ventricular pause; after 2 seconds, the pause criterion is fulfilled (programmable parameter: pause of 2, 3 or 4 seconds); switch to DDD mode (vertical line);

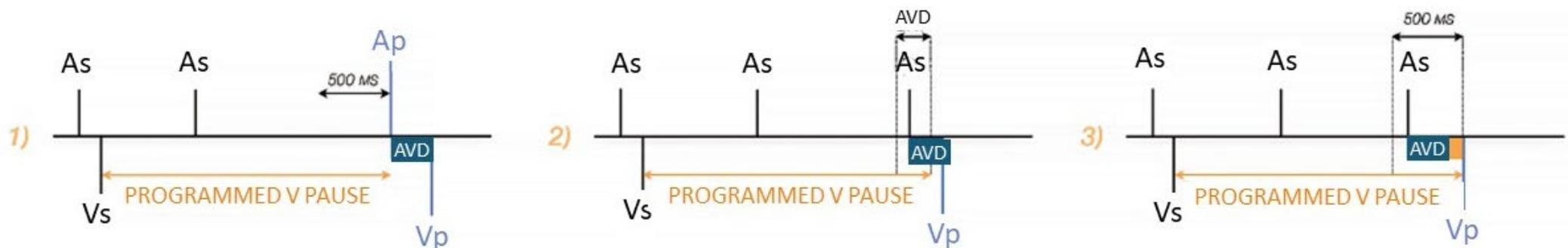
COMMENTAIRES

The fourth switch criterion to DDD mode is the presence of a programmable ventricular pause of 2, 3 or 4 seconds. The duration of the ventricular pause may slightly exceed the programmed value such that atrioventricular activation can be synchronized at the time of the mode switch:

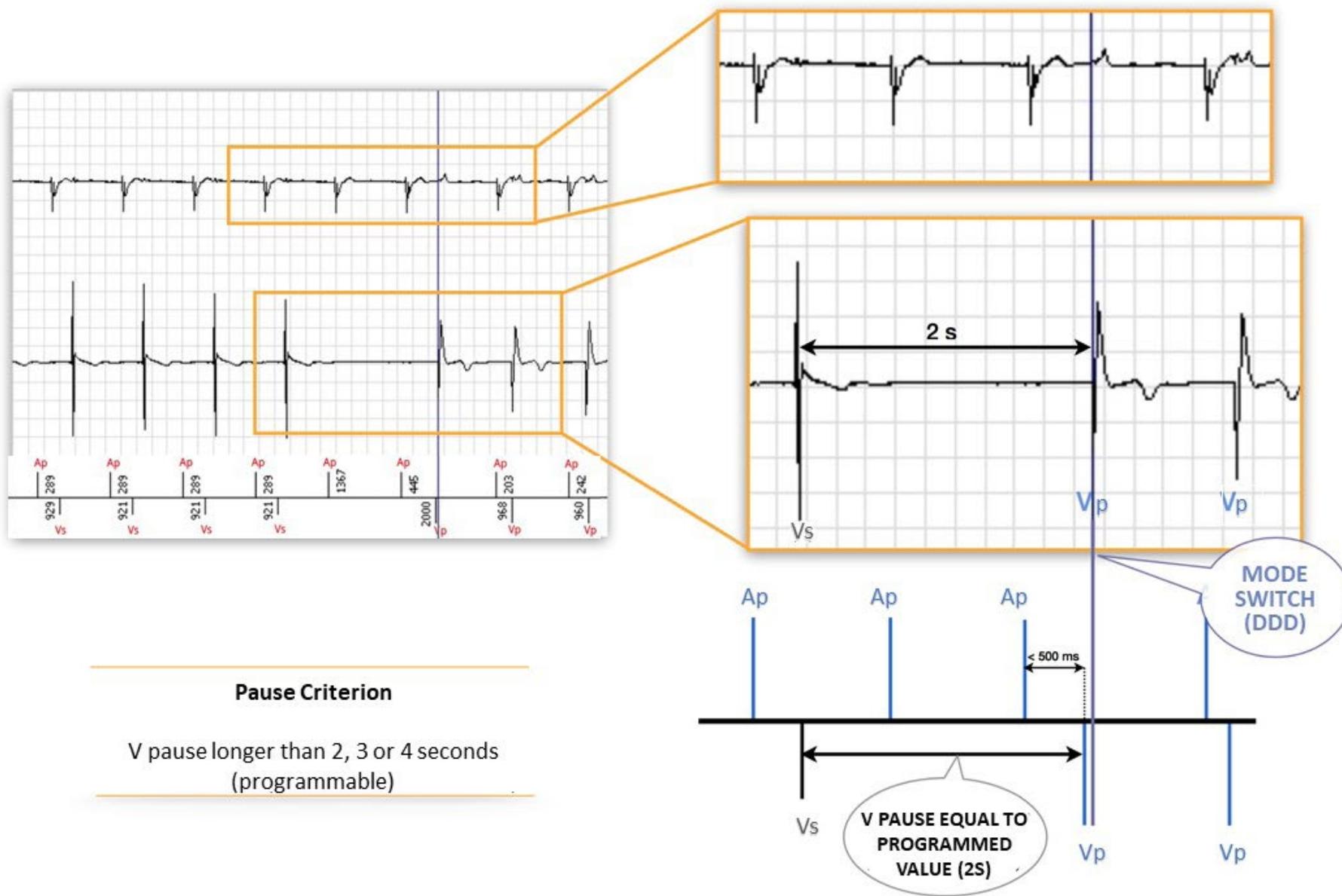
- the duration of the pause corresponds to the programmed value + the AV delay at rest: this case occurs when no atrial depolarization has occurred within 500 ms preceding the end of the programmed pause; the device paces the atrium at the end of the programmed pause, followed by the ventricle at the end of the programmed AV delay and then switches to DDD mode.
- the duration of the pause corresponds to the programmed value + a shorter duration than the AV delay at rest: this case occurs when the intrinsic atrial depolarization occurs just before the end of the programmed pause (value less than the programmed AV delay); the device paces the ventricle at the end of the programmed AV delay and then switches to DDD mode.

- the duration of the pause corresponds to the programmed value: this occurs when an intrinsic atrial depolarization occurs within 500 ms preceding the end of the duration of the programmed pause; the device prolongs the AV delay over one cycle to pace exactly at the end of the programmed duration of the pause and then switches to DDD mode.

When the rate is programmed in the conventional manner (in the order of 50 to 60 bpm), the pause and AVB III criteria can overlap or be exclusive. Indeed, in this case, if the pause is programmed at 4 seconds, the AVB III criterion (2 consecutive atrial activities) will be fulfilled before the pause criterion and the maximum duration of the pause will never be reached. In contrast, when the pause criterion is programmed at 3 seconds, the 2 criteria can be fulfilled on the same tracing.



The pause criterion was designed to prevent the occurrence of a prolonged ventricular pause exceeding 2, 3 or 4 seconds. When the minimum rate is set to 60 bpm, a pause time of 4 seconds cannot be reached, the AVB III criterion being fulfilled beforehand.



Patient

67-year-old man implanted with a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction and paroxysmal AV block;

Quiz

What is(are) the correct answer(s) regarding the SafeR mode when the pacemaker has switched to DDD mode?

- A. the pacemaker switches back to ADI mode after 10 consecutive sensed ventricular events
- B. the pacemaker switches back to ADI mode after 12 consecutive sensed ventricular events
- C. the pacemaker automatically switches back to ADI mode after 100 paced ventricular cycles
- D. the pacemaker automatically switches back to ADI mode after 50 paced ventricular cycles
- E. the pacemaker automatically switches back to ADI mode after 20 paced ventricular cycles



TRACING

At the beginning of the tracing, atrial pacing (A) and ventricular pacing (V); after 100 paced ventricular cycles, to ADI mode; AVB III criterion fulfilled (2 consecutive blocked paced atrial complexes); new switch to DDD mode (vertical line);

COMMENTS

In the preceding tracings, we described the 4 criteria allowing switch from ADI mode to DDD mode at regular intervals. The pacemaker searches for the presence of normal atrioventricular conduction. Deep understanding of the search of atrioventricular conduction when the pacemaker has switched to DDD mode is essential to understand the different right ventricular pacing reduction algorithms. Indeed, the underlying philosophies differ according to the manufacturers leading to differences in effectiveness and presence of complications. Schematically, 2 options are opposed: 1) AV delay hysteresis (Boston Scientific, St Jude Medical and Biotronik) with a risk of triggering PMT episodes but without the possibility too see the blocked P waves, 2) switch to ADI mode (MicroPort™, Medtronic) with a reduced risk of PMT and the possibility to observe a ventricular pause if atrioventricular conduction is permanently impaired.

For MicroPort™ pacemakers (SafeR algorithm), when the pacemaker has switched to DDD mode, the search for the return to normal atrioventricular conduction occurs:

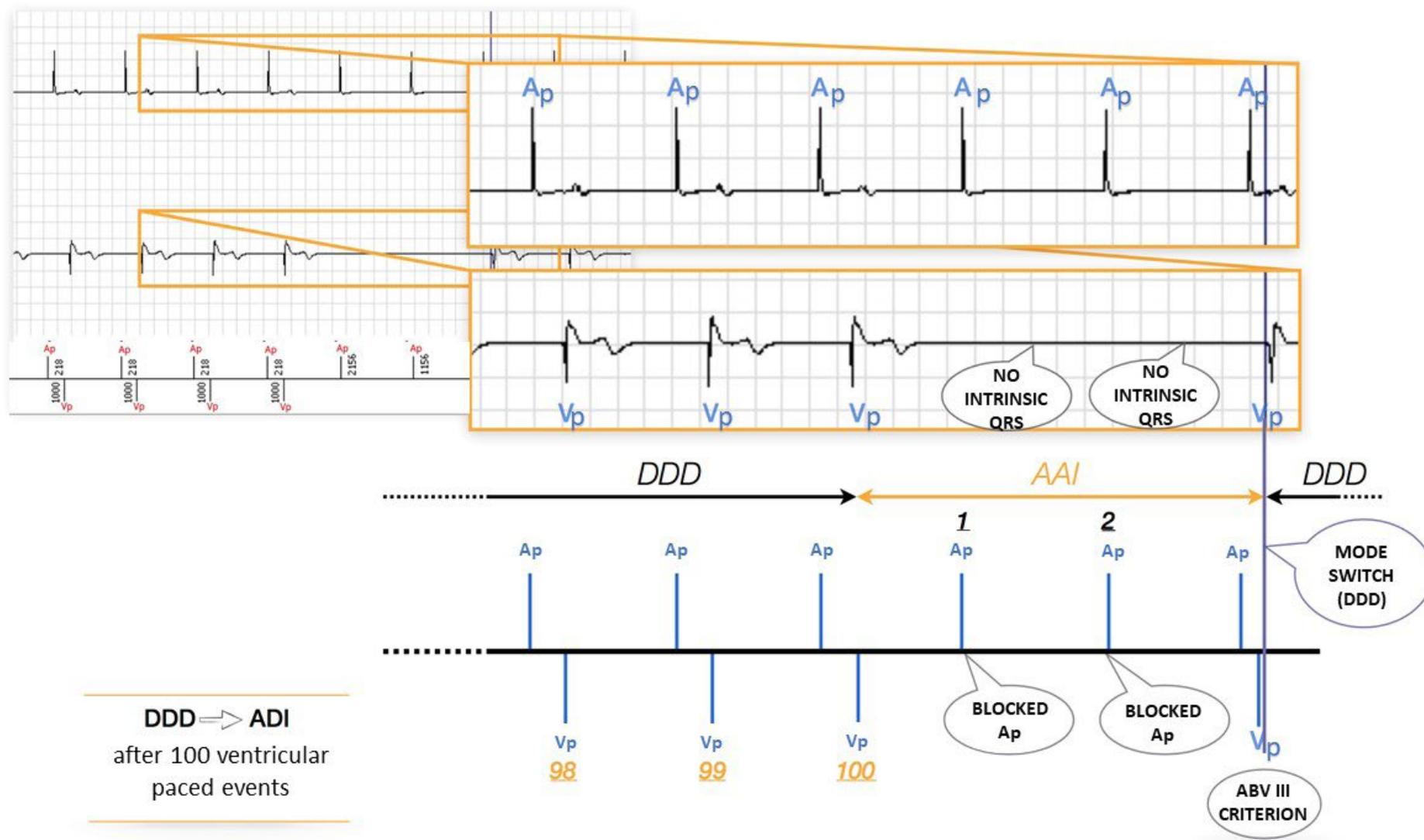
- after sensing 12 consecutive ventricular events (operation in DDD mode but 12 consecutive AP or VS cycles);
- automatically every 100 paced ventricular cycles;

These 2 parameters are not programmable. In order to search for a return to

atrioventricular conduction, the pacemaker switches back to ADI mode. The 4 criteria of the algorithm described above are then applied to switch back to the DDD mode if the AV conduction didn't resume. During this search, a ventricular pause and blocked P waves can therefore be observed as in the current example. In a patient with permanent atrioventricular block, it is better to avoid too many search sequences: ventricular pauses can be symptomatic. There are a number of "durable" switch criteria in DDD mode when atrioventricular conduction is permanently impaired. The pacemaker switch to DDD mode overnight until 8 a.m. the next morning when the pacemaker has recorded:

- more than 45 episodes of AV block during the last 24 hours
- more than 15 episodes of AV block per 24 hours for 3 consecutive days
- more than 50% of the time spent in DDD mode during one hour

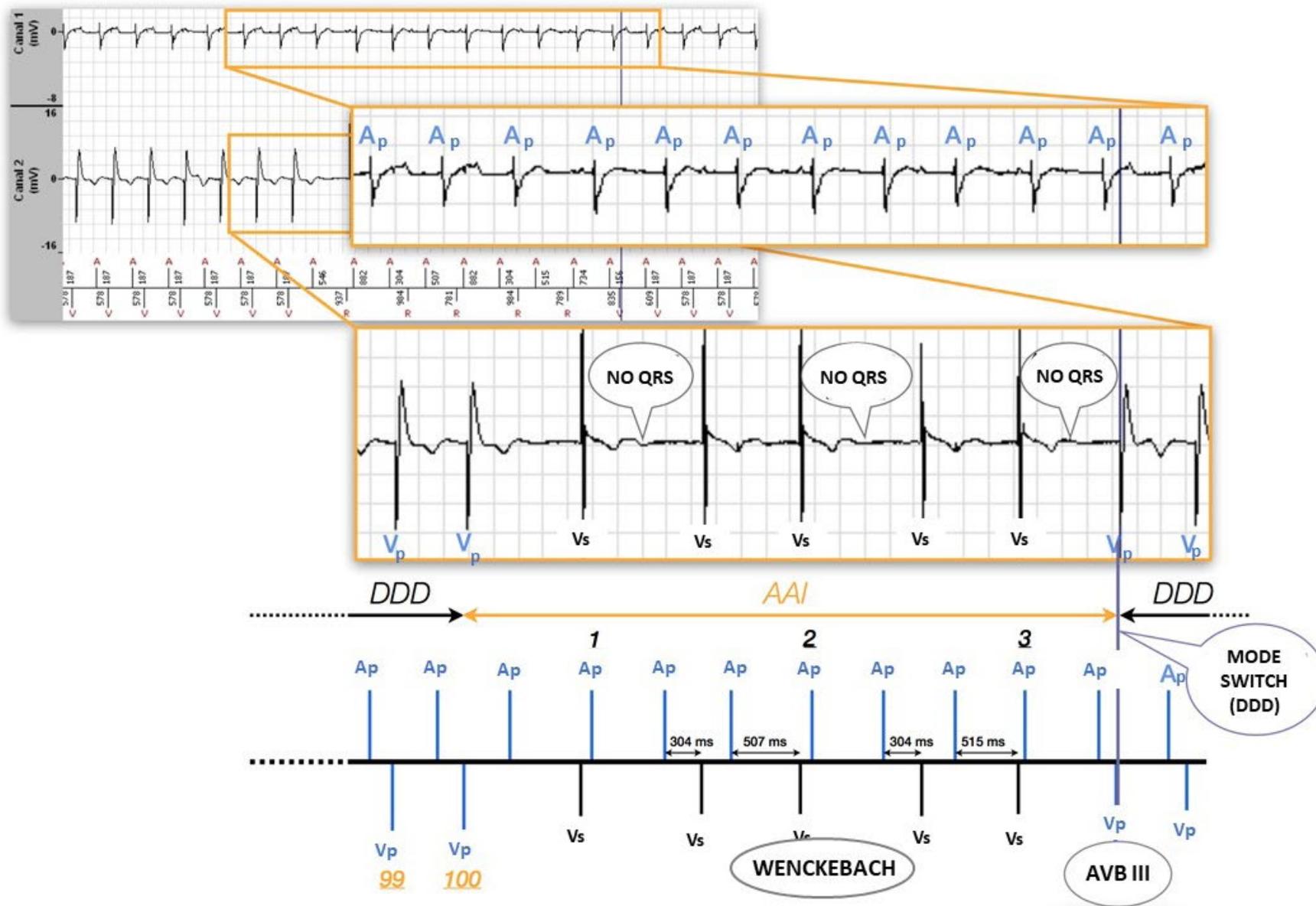
When the pacemaker has switched to DDD mode, the device searches for the return of normal atrioventricular conduction by switching back to ADI mode. The 4 criteria of the SafeR algorithm are then applied to possibly revert to DDD mode with a risk of episodic occurrence of ventricular pauses.



Tracing 21: DDD-ADI switch

TRACING

At the beginning of the tracing, atrial pacing (Ap) and ventricular pacing (Vp); after 100 ventricular paced cycles, return to ADI mode; AVB II criterion fulfilled with 3 non-consecutive blocked atrial paced complexes (non-programmable parameter, 3 in 12 blocked atrial activities); new switch to DDD mode (vertical line);



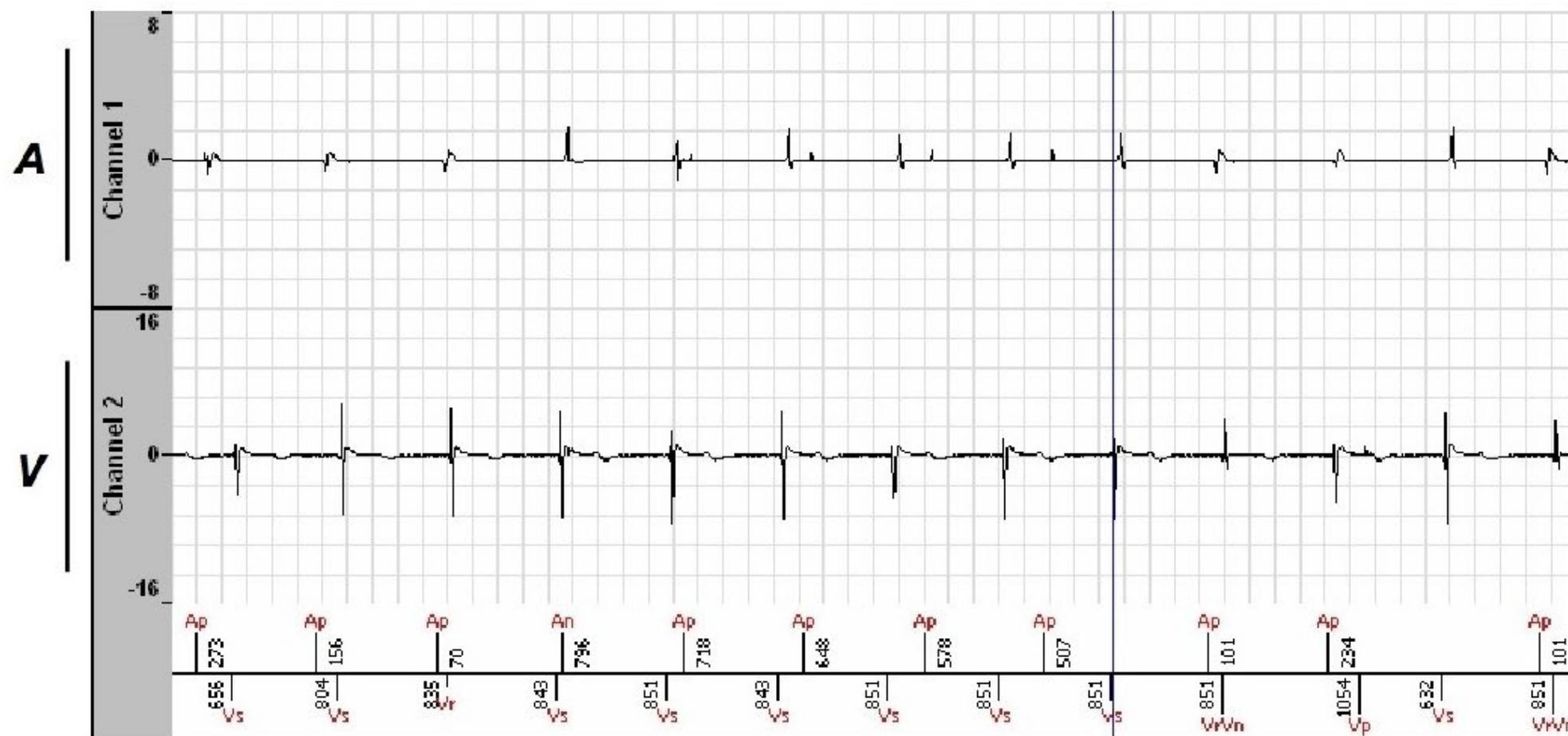
Patient

66-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM and ECG, what is(are) the correct answer(s)?

- A. the pacemaker switches to DDD mode according to the AVB I criterion
- B. the pacemaker switches to DDD mode according to the AVB II criterion
- C. the pacemaker switches to DDD mode according to the AVB III criterion
- D. the pacemaker switches to DDD mode on the pause criterion
- E. this tracing shows an atrioventricular conduction disorder



TRACING

This tracing shows inappropriate switch to DDD mode in the absence of atrioventricular conduction disorder, the AVB 1 criterion being fulfilled on an active junctional rhythm; initially, rate responsive atrial pacing and intrinsic atrioventricular conduction; slight acceleration of the ventricular rhythm probably because of active junctional rhythm; a complex marked Vr (third cycle of the tracing) corresponds to ventricular sensing in the safety window (absence of committed pacing during operation in SafeR mode); ventricular activation being slightly faster than the atrial pacing rate, the ventricular complexes progressively precede atrial pacing and occur immediately before marker Ap yielding a long Ap-Vs pseudo-pattern; the Ap-Vs pseudo-intervals gradually decrease but remain higher than the programmed value; after 6 consecutive cycles, the pacemaker switches to DDD mode (vertical line); note that in the first cycle, ventricular sensing r occurs in a safety window triggering a committed ventricular pacing (Vn) after a short AV delay of 95 ms at the end of the safety window (normal operation of the DDD mode); on the second cycle, ventricular sensing r occurs in the post-atrial ventricular blanking and is therefore not detected (no inhibition of ventricular pacing, no committed pacing at the end of the safety window, and ventricular pacing at the end of programmed AV delay);

COMMENTS

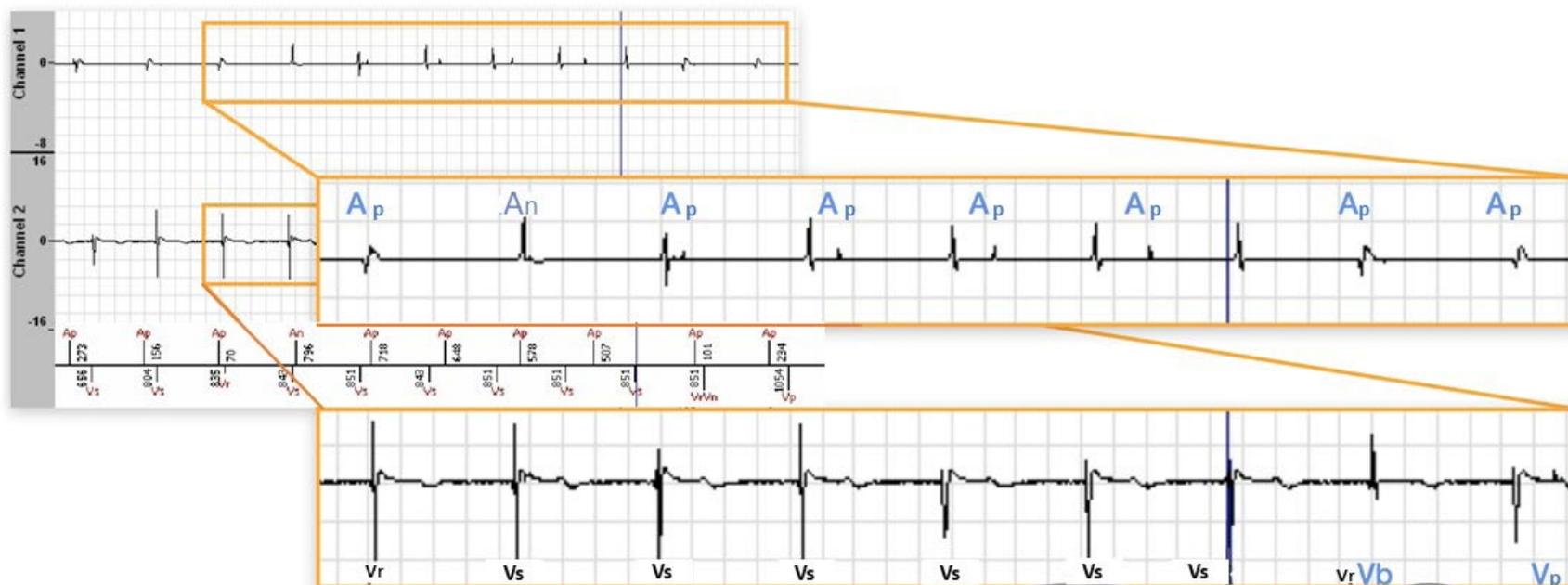
In SafeR mode, analysis of the episodes of mode switch to DDD highlights a certain number of surprising patterns. One of the common causes of inappropriate switch (absence of atrioventricular conduction disorder) is the presence of an active idioventricular or junctional rhythm and isorhythmic dissociation. The SafeR mode is predominantly programmed in patients with sinus dysfunction and preserved atrioventricular conduction. In some patients, there may be an increased automaticity at an ectopic focus (most often the atrioventricular node) which generates a so-called active rhythm that competes with activation stemming from the atrium. When the nodal « escape » is clearly faster than the programmed atrial rate, retrograde atrial conduction is observed if ventricular-atrial conduction is preserved with 1:1 ventricular-atrial activation. In SafeR mode, the pacemaker does not switch according to an AVB II, III or pause criterion (absence of blocked « P wave », no pause). On the other hand, it can switch according to an AVB 1 criterion if, over several consecutive cycles, the Vs-As or Vs-Ap intervals are relatively short and consequently the As-Vs or Ap-Vs intervals are long.

When the rate of the active junctional rhythm is relatively similar to that of the P wave or atrial pacing, there may be a competition between the two rhythms and one can observe

capture or fusion complexes. There can also be a so-called isorhythmic dissociation, the atria and ventricles having an independent regular rhythm in the absence of atrioventricular conduction disorders. When the junctional rhythm is slightly faster than the pacing rate as observed in this example, intrinsic ventricular activity may precede atrial pacing and yield a pseudo-pattern of long As-Vs or Ap-Vs leading to mode switch.

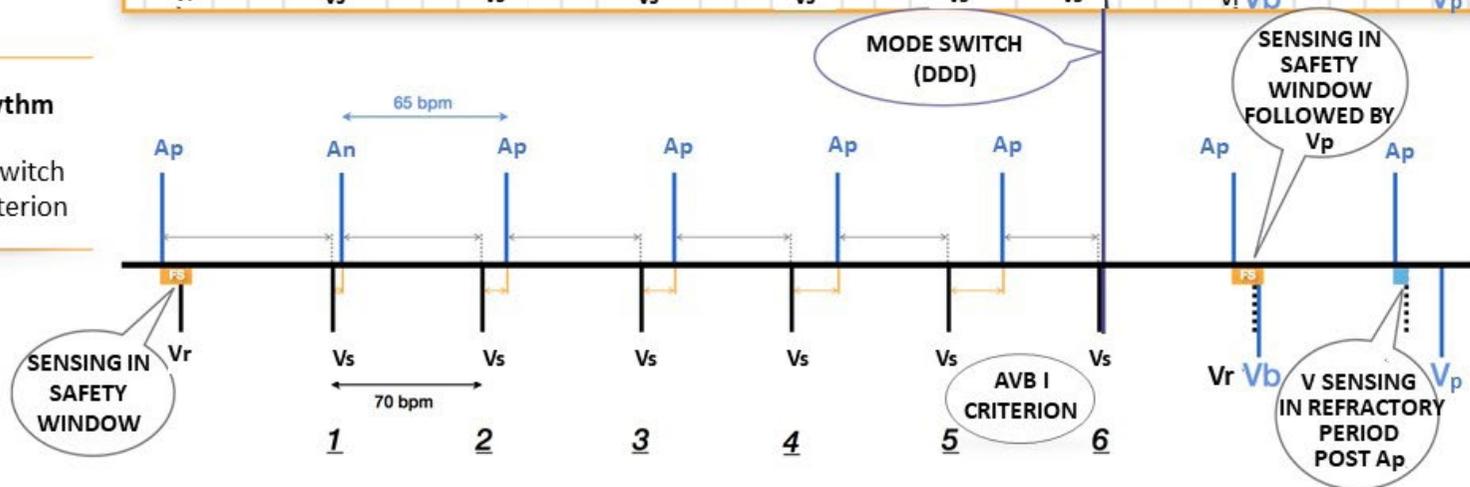
Analysis of the device memory quite frequently shows this type of episodes in patients with sinus dysfunction. Their number per patient, however, is most often limited, leads to a slight increase of ventricular pacing percentage. Increasing in the basic rate and programming of a rate response allows eliminate or considerably reduce the occurrence of this type of switch, which is generally asymptomatic and insofar as they are rare, not induce changes in programming. Indeed, while the switch can, strictly-speaking, be deemed inappropriate (absence of atrioventricular conduction disorder), and appear relatively adapted to restore the physiological atrioventricular synchrony.

Patients with sinus dysfunction programmed in SafeR mode may exhibit asymptomatic active junctional episodes highlighted as a result of inappropriate switch according to a AVB I criterion.



Junctional Rhythm

inappropriate switch due to AVB I criterion



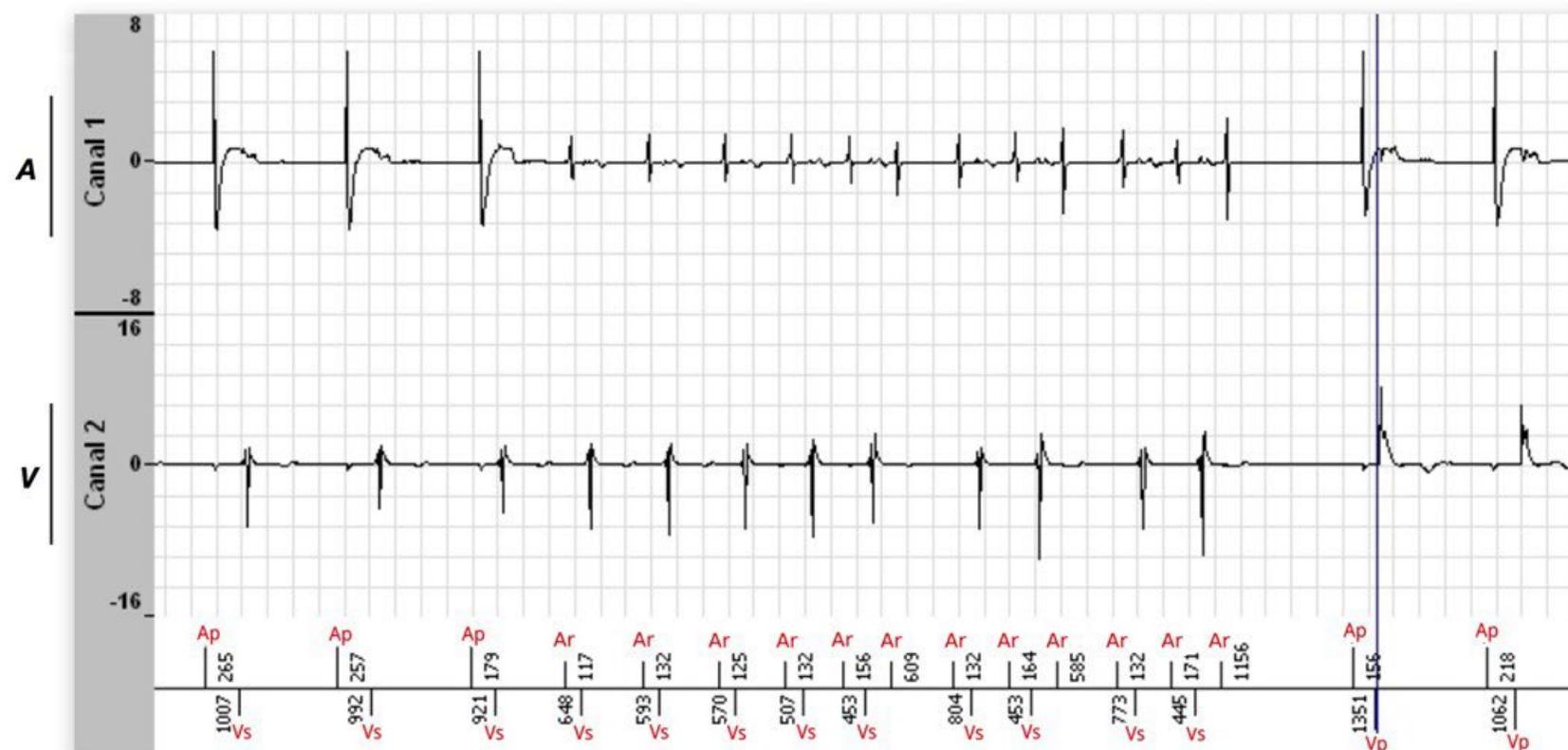
Patient

72-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM and ECG, what is(are) the correct answer(s)?

- A. the pacemaker switches to DDD mode according to the AVB I criterion
- B. the pacemaker switches to DDD mode according to the AVB II criterion
- C. the switch occurs on an episode of non-sustained atrial arrhythmia
- D. the switch occurs on an episode of sustained atrial arrhythmia
- E. the switch occurs on an episode of ventricular arrhythmia



TRACING

This tracing shows inappropriate switch to DDD mode in the absence of atrioventricular conduction disorder, the AVB II criterion being fulfilled on a non-sustained atrial arrhythmia episode; at the beginning of the tracing, atrial pacing at the minimum rate and intrinsic atrioventricular conduction (classic sinus dysfunction pattern); initiation of an atrial arrhythmia with a relatively mildly premature first cycle; during this episode, atrial sensing occurs outside the refractory periods and the cycles are classified as P; after 3 atrial cycles (P) not sensed at the ventricular level (blocked « P waves »), the AVB II criterion is fulfilled (at least 3 blocked P waves out of 12); switching to DDD mode (vertical line); termination of arrhythmia and atrial and ventricular pacing (probably unnecessary ventricular pacing);

COMMENTS

These 2 tracings illustrate episodes of mode switching to DDD in conjunction with the occurrence of atrial arrhythmia (non-sustained atrial tachycardia or blocked premature atrial contractions) and leading to unnecessary ventricular pacing, with preserved atrioventricular conduction.

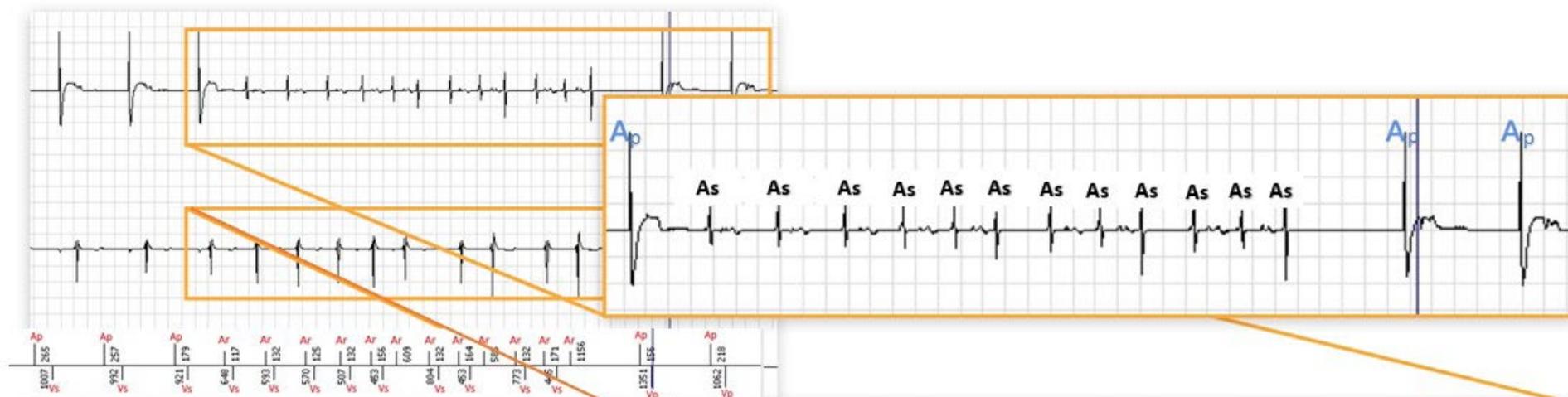
When the pacemaker operates in SafeR mode, following atrial sensing or pacing, a non-programmable relative refractory period is triggered at the atrial stage. Its duration is dynamic and is calculated according to the atrial rate. Its purpose is to detect the acceleration of the atrial rhythm (hence its name: WARAD for Window of Atrial Rate Acceleration Detection). When the atrial rate is less than 80 bpm, the WARAD is 62.5% of the previous P-P (or A-A) interval. When the atrial rate is greater than (or equal to) 80 bpm, the WARAD represents 75% of the previous P-P interval. All atrial events sensed in the WARAD are noted by markers in refractory periods (small « p »). When a premature atrial contraction occurs in the WARAD, the value of the WARAD is then fixed to that of the WARAD calculated on the sinus cycle prior to the very first PAC. It cannot exceed 500 ms.

On the tracing with blocked premature atrial contractions, the initial atrial rate is less than 80 bpm, the prematurity of the extrasystole is poor (the first PAC cycle is longer than 62.5% of the previous AA cycle), which explains that the extrasystoles are labeled P and not p because occurring outside the WARAD. Similarly, on the tracing with the non-sustained atrial arrhythmia, the initial atrial rate is less than 80 bpm and the prematurity of the first arrhythmic beat is also poor (the first PAC cycle is longer than 62.5% of the previous AA cycle), which also explains the marker P and not p because occurring outside the WARAD. The acceleration of the atrial rate is hence progressive, with the WARAD adapting cycle to cycle. No atrial cycle falls in the WARAD and all cycles are classified P. In SafeR mode, the switching to the DDD mode is based on the presence of intrinsic

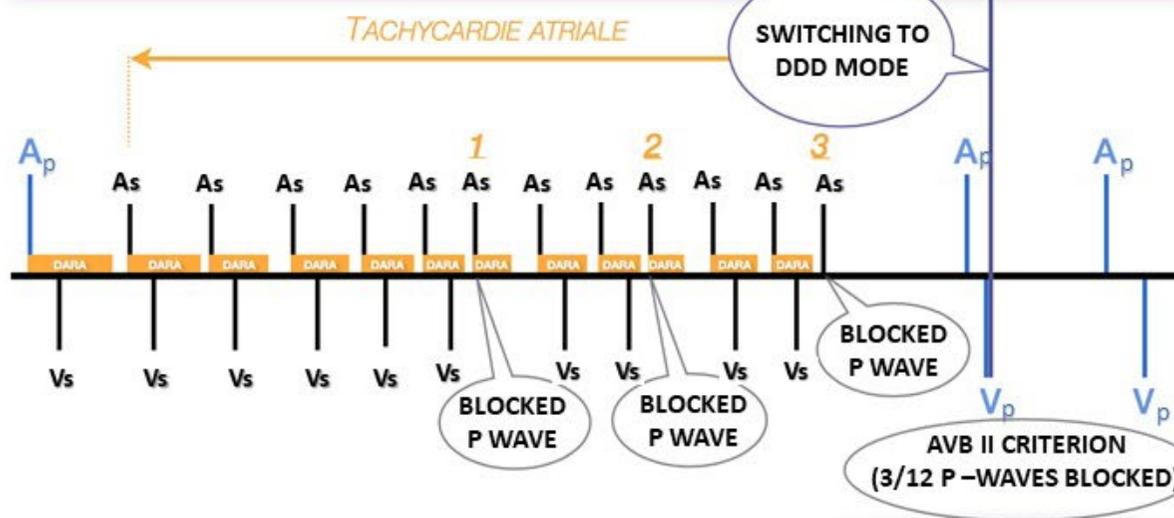
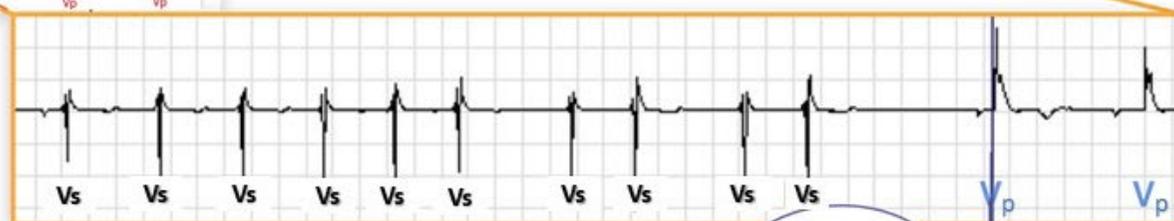
atrial activities outside refractory periods (P) or blocked paced atrial complexes (A) or the presence of long PR or AR intervals. The atrial cycles sensed in the WARAD (p) are excluded from this analysis since the device suspects an onset of atrial arrhythmia that can physiologically impair the quality of atrioventricular conduction. Given a suspicion of the onset of atrial arrhythmia (succession of cycles classified as p), the only valid remaining switching criterion is that of ventricular pause (not the AVB I, AVB II or AVB III criteria). After sensing of a PAC in the WARAD, the Pause criterion is temporarily forced to 2 seconds during the next 12 ventricular cycles.

In patients with frequent blocked premature atrial contractions detected outside of the WARAD (at least 3 in 12), the number of mode switches according to the AVB II criterion will be substantial, thereby increasing the percentage of « unnecessary » ventricular pacing. Similarly, in patients with atrial arrhythmia with non-sudden onset (first atrial cycle outside of the WARAD), it is common to observe switches 1) according to AVB 1: when the atrial rate is relatively high but below Wenckebach's point, a 1:1 conduction is observed at the occasional cost of a prolongation of the PR interval which can sometimes exceed the duration limit of the AVB I criterion, especially since this value is adaptive according to the heart rate (the faster the rate, the smaller the value). To prevent such inappropriate switching and ensuing unnecessary ventricular pacing, it may be useful to program a relatively significantly long PR value with no variation as a function of rate (max PR = min PR); 2) according to AVB II or AVB III: , when the atrial rate is relatively fast, a certain number of intermittent (AVB II criterion) or successive (AVB III criterion) atrial activities outside of the WARAD can be blocked. Since the WARAD is not programmable, there are no programming modifications to propose to reduce the incidence of inappropriate switch, which is usually responsible for a slight increase in the percentage of ventricular pacing.

The interrogation of the pacemaker memory can highlight a number of inappropriate switching to the DDD mode (AVB I, AVB II or AVB III criteria) related to the occurrence of atrial arrhythmia episodes or blocked premature atrial contractions.



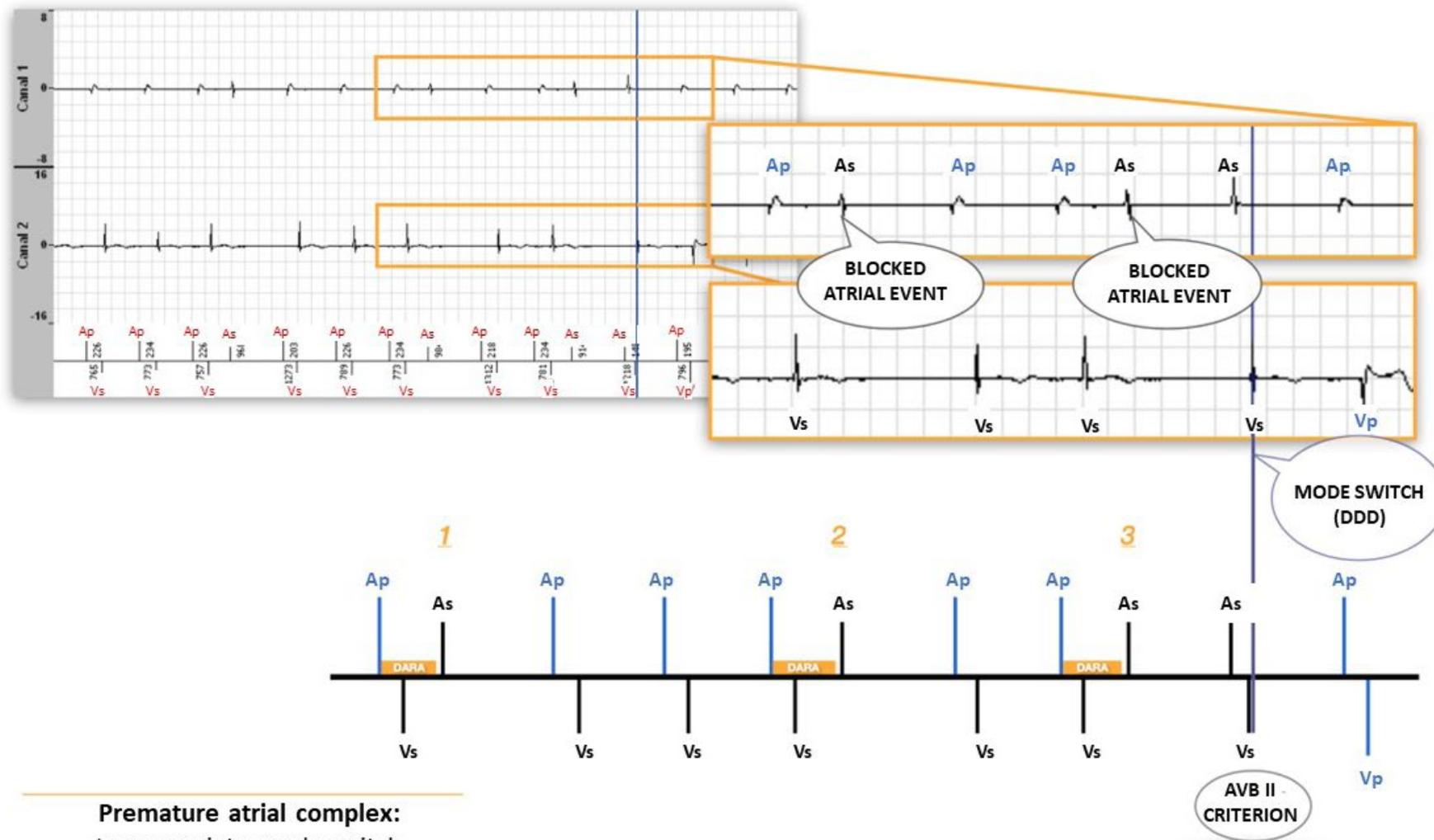
Atrial Arrhythmia:
Inappropriate Mode Switch due to AVB II criterion



Tracing 24: Inappropriate AVB II criterion

TRACING

This tracing shows inappropriate switch to DDD mode in the absence of atrioventricular conduction disorder, the AVB II criterion being fulfilled by the occurrence of 3 blocked premature atrial contractions; at the beginning of the tracing, atrial pacing at the controlled rate and intrinsic atrioventricular conduction (classic sinus dysfunction pattern); first premature atrial contraction classified as As because relatively premature; absence of atrioventricular conduction on this extrasystole (blocked « P wave »); resumption of spontaneous atrioventricular conduction on atrial pacing; after 3 blocked premature atrial contractions, switch to DDD mode (vertical line); atrial and ventricular pacing (probably unnecessary ventricular pacing);



Premature atrial complex:
 Inappropriate mode switch
 due to AVB II criterion

Patient

77-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM and ECG, what is(are) the correct answer(s)?

- A. the pacemaker switches to DDD mode according to the AVB III criterion
- B. the pacemaker switches to DDD mode according to the pause criterion
- C. the switch occurs due to paroxysmal atrioventricular conduction disorder
- D. the switch occurs as a result of the occurrence of a premature ventricular contraction occurring in the post-atrial ventricular blanking
- E. the switch occurs as a result of the occurrence of a premature ventricular contraction occurring in the post-atrial atrial blanking



TRACING

This tracing shows inappropriate switch to DDD mode in the absence of atrioventricular conduction disorder, the pause criterion is fulfilled following a premature ventricular contraction occurring during the post-atrial ventricular blanking; at the beginning of the tracing, atrial pacing at the minimum rate and intrinsic atrioventricular conduction (classic sinus dysfunction pattern); premature ventricular contraction occurring simultaneously with atrial pacing and undetected because occurring in the post-atrial ventricular blanking; the pause criterion (2 seconds) is fulfilled; switch to DDD mode (vertical line); atrial and ventricular pacing (likely unnecessary ventricular pacing);

COMMENTS

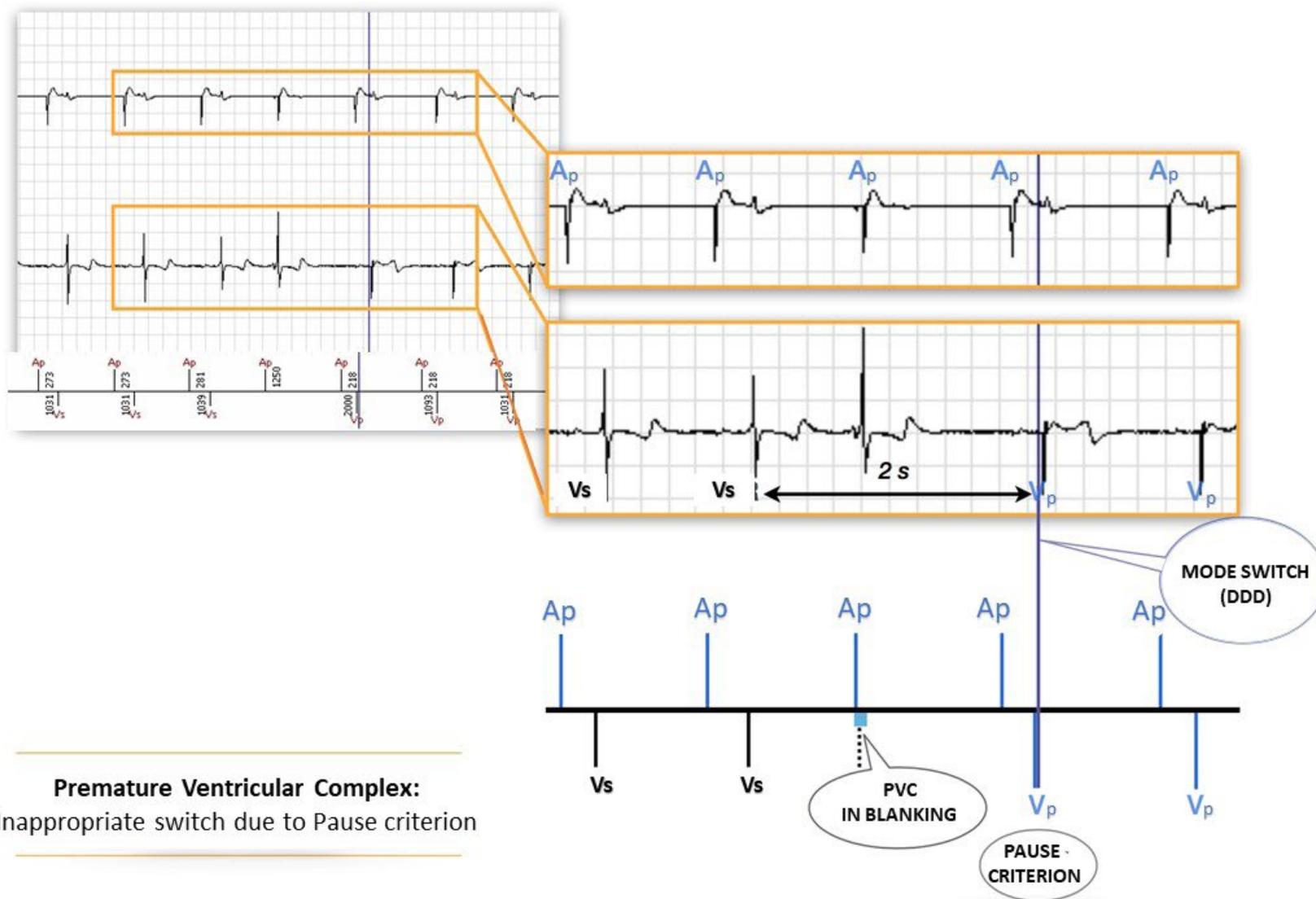
These 2 tracings illustrate episodes of inappropriate switch from AD mode to DDD mode in conjunction with the occurrence of a premature ventricular contraction.

In the first tracing, the premature ventricular contraction is not sensed since it occurs in the post-atrial ventricular blanking. The pacemaker operates in AAI mode with a ventricular sensing channel functioning independently diagnose the occurrence of a paroxysmal atrioventricular conduction disorder. However, the 2 channels (atrial and ventricular) not totally independant. Indeed, it is essential to « protect » the ventricular channel against the AV- crosstalk following atrial pacing: as for conventional DDD mode, there is the post-atrial ventricular blanking followed by safety window. If atrial pacing is blocked, signal that falls in the ventricular blanking is not be sensed, thereby leading to appropriate switch. On the other hand, if the event is a premature ventricular contraction as in this example, this leads to inappropriate switch.

In the second tracing, the premature ventricular contraction occurs outside of any refractory period. The ensuing compensatory pause leads to inappropriate switch.

The duration of the pause is programmable: 2, 3, 4 seconds. In order to dramatically reduce this type of switch, it may be useful to set a pause time of 4 seconds, its incidence being much higher for a duration of 2 seconds. This reduces the number of switches and the percentage of unnecessary ventricular pacing while preventing the increased risk of symptoms in the presence of an atrioventricular block episode. Indeed, if the basic rate is programmed at 60 bpm, and atrioventricular conduction is interrupted, the AVB III criterion fulfilled before the occurrence of a 4-second pause.

The occurrence of ventricular extrasystoles may favour inappropriate switching to the DDD mode, especially as the extrasystoles are relatively late (contemporaneous with the atrial pacing) and the duration of the pause is set to 2 seconds.

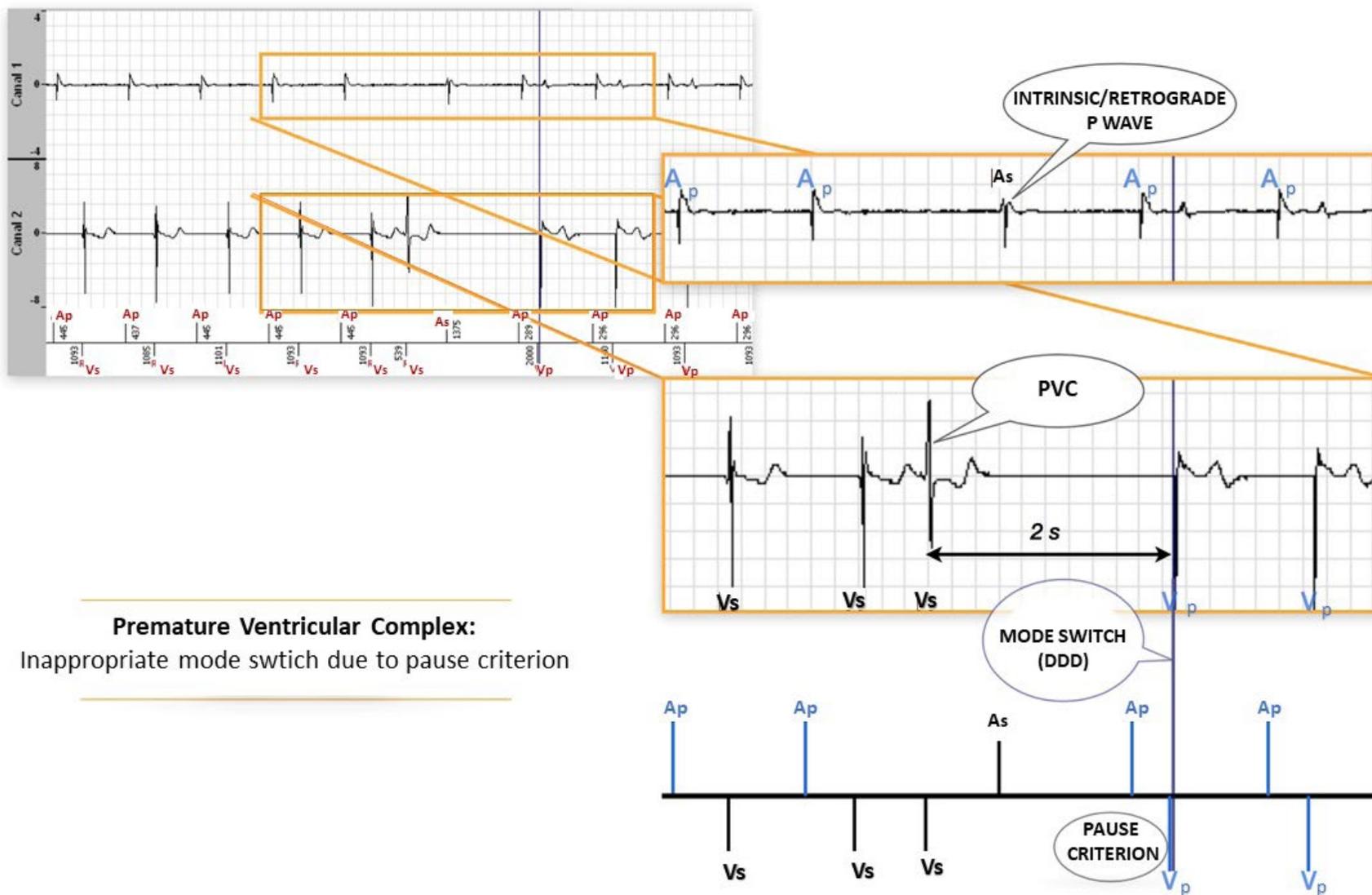


Premature Ventricular Complex:
Inappropriate switch due to Pause criterion

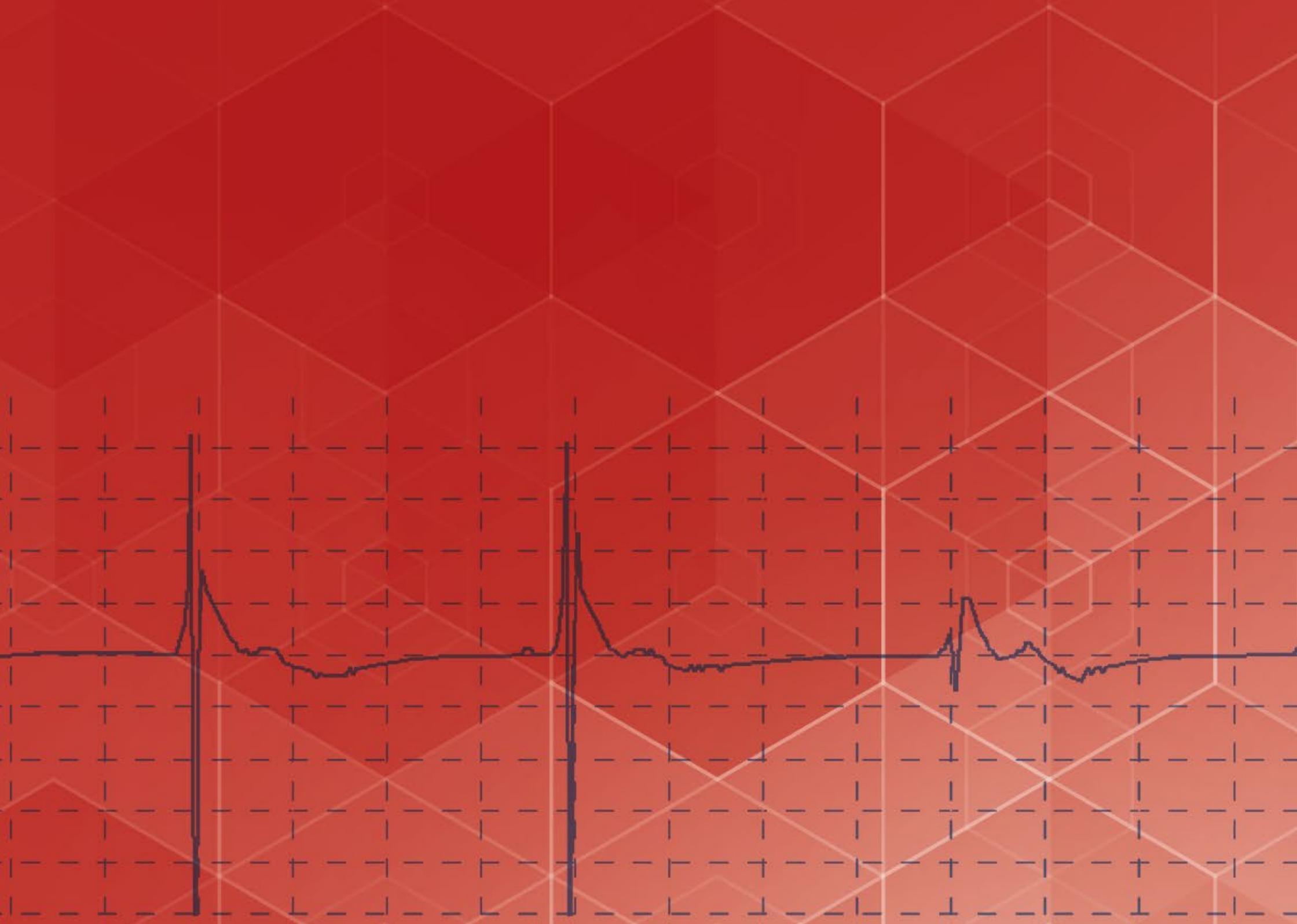
Tracing 26: Inappropriate pause criterion

TRACING

This tracing shows inappropriate switch to DDD mode in the absence of atrioventricular conduction disorder, the pause criterion being fulfilled following a premature ventricular contraction; at the beginning of the tracing, atrial pacing at the basic rate and intrinsic atrioventricular conduction (classic sinus dysfunction pattern); premature ventricular contraction followed by atrial activity outside of any refractory period and classified as As (no triggered AV delay); ventricular pause of 2 seconds; switch to DDD mode (vertical line) and atrial and ventricular pacing (ventricular pacing likely unnecessary);



Premature Ventricular Complex:
Inappropriate mode switch due to pause criterion



Pacemaker **chapter 3**

Pacing



Patient

71-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the pacemaker switches according to an AVB I criterion
- B. the pacemaker switches according to an AVB II criterion
- C. there are ventricular sensing failures
- D. there are losses of ventricular capture
- E. there are losses of atrial capture



TRACING

Atrial pacing (Ap) and ventricular sensing (Vs); prolongation of the Ap-Vs interval exceeding the programmed long Ap-Vs value over 6 consecutive cycles during physical effort; switching to DDD mode (vertical line) and ventricular pacing (Ap-Vp cycles) with programmed AV delay; absence of ventricular capture with visualization of ventriculograms corresponding to intrinsic and conducted QRS; absence of sensing of the ventricular signal when occurring immediately after the ventricular pacing artifact since falling in the post-ventricular ventricular blanking; proper sensing when the R wave occurs remotely from ventricular pacing (Ap-Vp-Vs cycle) with recycling of the pacing interval;

COMMENTS

This patient presented mode switches of first degree AV block criterion. The recorded tracings allowed to show intermittent loss of ventricular capture without any change in the sensing quality. Chest X-ray revealed no lead dislodgement. The threshold increase could be explained by the introduction of flecainide treatment for atrial fibrillation. Changing the programming (increasing the output amplitude) enabled solve the problem.

The pacing threshold corresponds to the smallest electrical impulse, delivered outside of all natural refractory periods, and able to generate depolarization. It can be measured in voltage (volts) or pulse width (milliseconds).

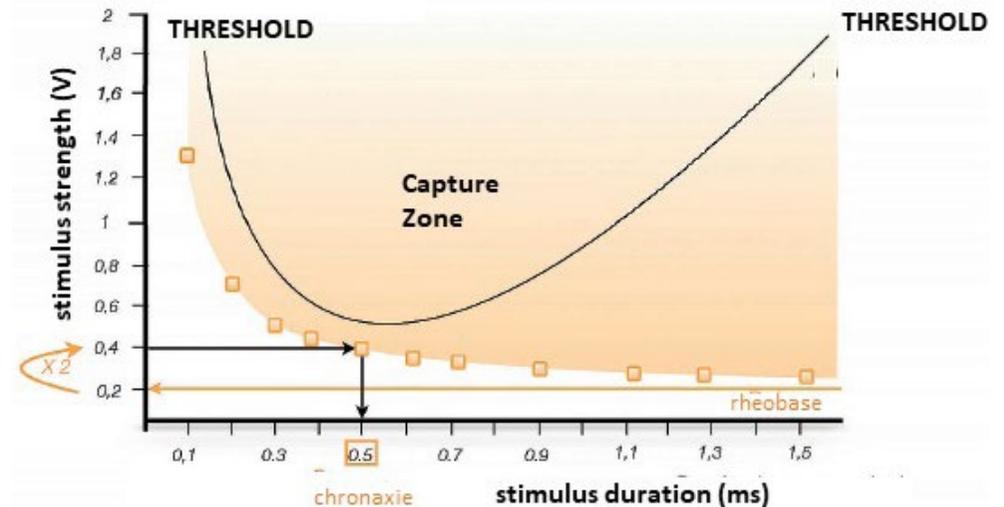
The Lapicque relationship, voltage-duration relationship, or rheobase-chronaxie, describes the nonlinear relationship of the threshold voltage relative to pulse duration. The amplitude at the pacing threshold increases significantly with a decrease in pulse duration (in practice below 0.2 ms). All points defined by their voltage and pulse duration located above the curve are associated with effective pacing, as opposed to those located below the curve.

Rheobase is the minimum current of infinite duration required to trigger a response (in practice, greater than 2 ms).

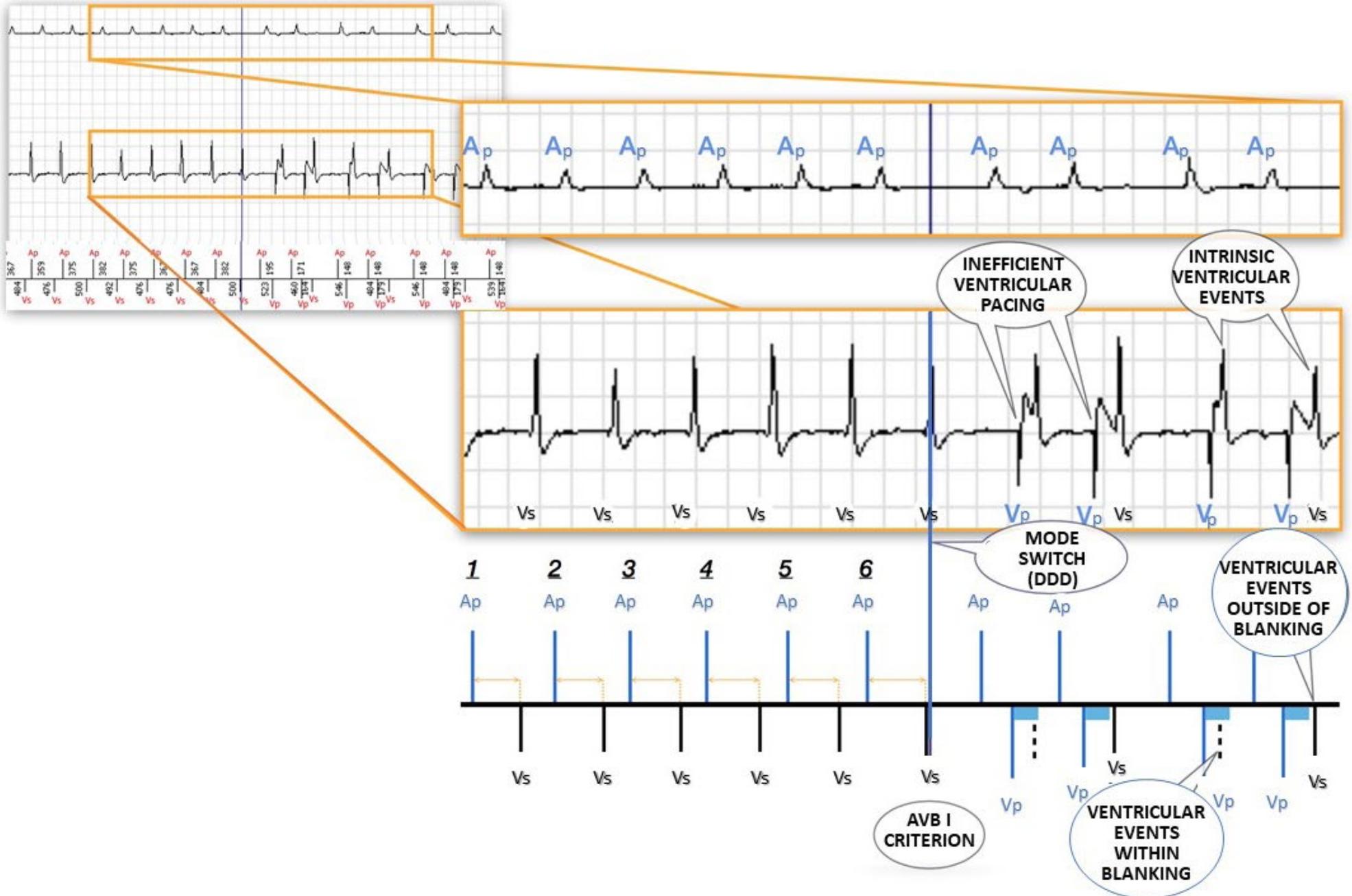
Chronaxie is the smallest effective pulse duration at twice the rheobase current. The energy consumed is minimal for a pulse duration corresponding to the chronaxie. Chronaxie and rheobase electrically qualify a pacing electrode. Nowadays, chronaxie

values are found between 0.3 and 0.4 ms regardless of the lead; this value corresponds to the typical nominal pulse width value of the pacemakers. Chronaxie is often longer on left ventricular pacing electrodes.

The pacing threshold is usually lower when the stimulus voltage is gradually decreased than when the stimulus is gradually increased: this is the Wedensky effect.



The assessment of the pacing threshold is of very important since the programming of the voltage and pulse duration is a prerequisite to establish the safety margin and determines the energy consumption of the device and hence the depletion rate of the batteries. It is generally recommended to program a safety margin of 100% which corresponds to double the threshold voltage. This safety margin is intended to take into account the circadian variations of the pacing threshold, which varies from one subject to another according to sleep, mealtime, physical activity, fever, etc.



Patient

65-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. when the ventricular autothreshold is on Auto, the ventricular pacing threshold is measured automatically every 6 hours
- B. when the ventricular autothreshold is on Auto, the ventricular pacing threshold measurement is based on the analysis of the evoked response
- C. when the ventricular autothreshold is on Auto, there is a cycle-to-cycle verification of ventricular capture
- D. when the ventricular autothreshold is on Monitor, the ventricular pacing threshold is measured every 6 hours
- E. when the ventricular autothreshold is on Monitor, there is an automatic adjustment of the pacing amplitude

TRACING

This tracing corresponds to an automatic threshold measurement performed by the device at the time of the interrogation; the capture test is initially based on a differentiation between polarization and evoked response and subsequently on a gradual decrease in pacing amplitude until loss of capture; on the tracing, there are 3 pacing pulses at 4 V (a single stimulus) with evaluation of the signal corresponding to the sum of the polarization at 4V + evoked response followed by 3 pacing pulses at 2 V (two stimuli with short VV delay) to evaluate the polarization at 2V + evoked response, thereby determining capture; the second displayed stimulus is a back-up safety pulse (in the event the pacing threshold is > 2V) which allows deducing the polarization; then follows a serial decrease in pacing amplitude (from 1.85 V during monitoring) in 0.15 V steps until loss of capture at 0.5 V with back-up safety pacing (second stimulus) to avoid the occurrence of a ventricular pause; threshold measured at 0.65 V;

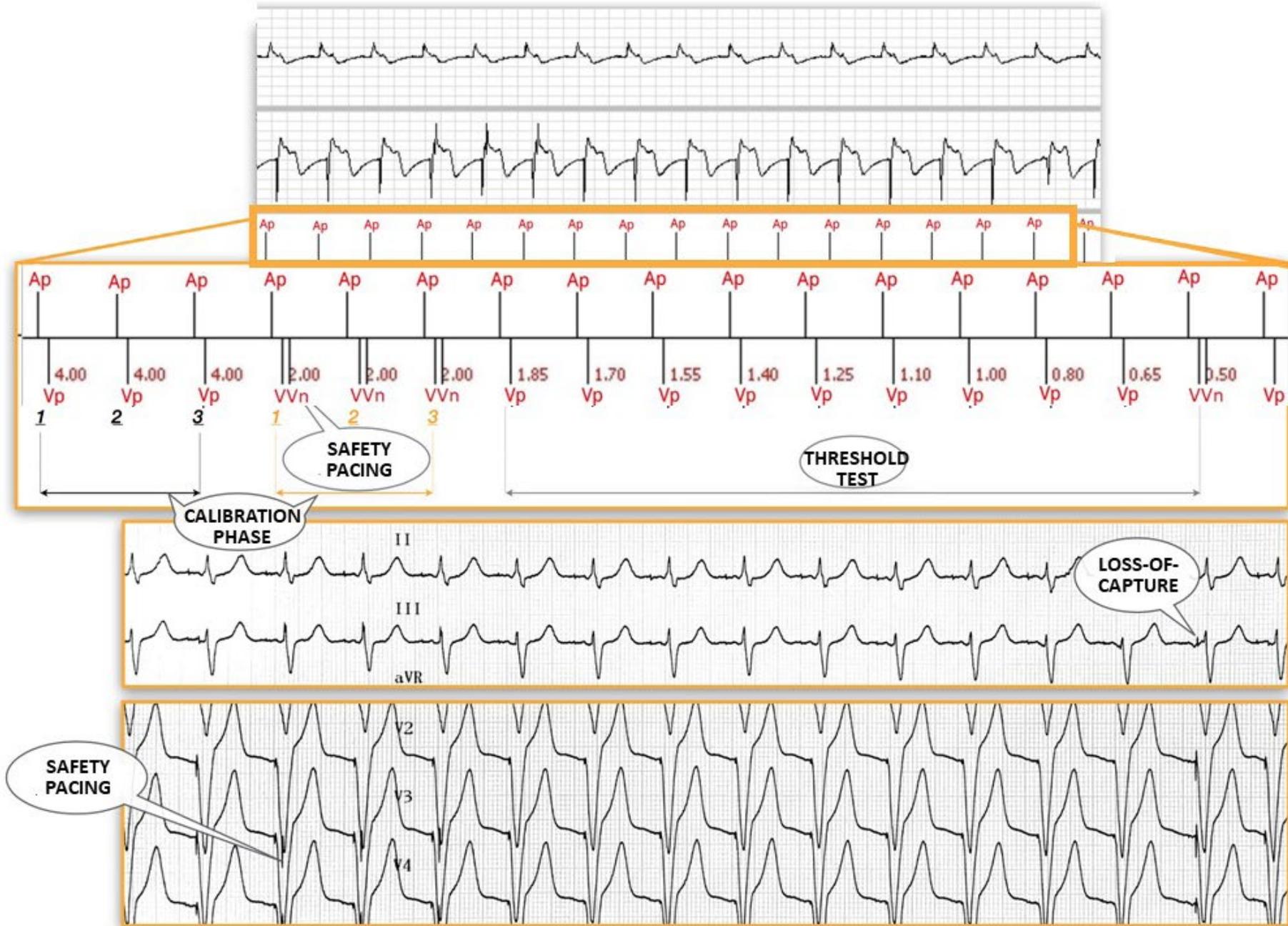
COMMENTS

It is now possible in all modern pacemakers to program a ventricular autothreshold measurement function, associated in varying degrees with either automatic adjustment of the pacing amplitude with cycle-to-cycle verification of capture effectiveness (Autocapture model allowing to deliver amplitudes close to the threshold with high amplitude safety pacing in the event of loss of capture) or by adjustment for extended durations by means of threshold tests performed at regular intervals but without cycle-to-cycle verification (Autothreshold model requiring larger margins). For MicroPort™ devices, the Autothreshold option was preferred. The Autothreshold function is based on 4 main principles: 1) the ventricular capture test is based on the differentiation between the evoked response potential (ERP) and the residual polarization of the lead (Polar); 2) when the autothreshold function is programmed to Auto, the device carries out automatic periodic measurements of the ventricular pacing threshold with adjustment of the programming; when the autothreshold function is programmed to Monitor, the device carries out automatic periodic measurements of the ventricular pacing threshold but without adjustment of the programming; when the autothreshold function is programmed to (No, Off), the device does not conduct automatic threshold measurements; 3) the automatic measurements are performed every 6 hours (4 measurements daily), with adjustment of the pacing amplitude for the next 6 hours (no cycle-to-cycle capture verification); 4) following the threshold measurement, the pacing amplitude is automatically adjusted (autothreshold on Auto) to twice the pacing threshold (100% safety margin) within the limit of a programmable minimum value (1.5, 2, 2.5, 3, 3.5 or 4 V);

The automatic threshold measurement can only be performed if the heart rate is below 95 bpm. The threshold measurement begins with a calibration phase with

2 objectives: to identify an initially high pacing threshold (greater than 2V) and to verify the proper differentiation between polarization (Polar) and evoked response potential (ERP). After an effective stimulus (ventricular capture), the 2 potentials are present (ERP + Polar) and measurable during a period of 65 ms, whereas after an ineffective stimulus, only the residual polarization of the lead is present (Polar) and measurable. During the threshold measurement, in order to increase the probability of ventricular capture without fusion with intrinsic activation, either the current AV delay is shortened by 65 ms (dual-chamber pacemaker) or the escape interval is shortened by 65 ms (single-chamber pacemaker).

The calibration phase consists of three pacing pulses at 4 V (at the programmed pulse width); the latest two are used to analyse the signal corresponding to both the evoked response and the polarization. These 3 pacing pulses are followed by 3 cycles with 2 ventricular pulses each: the first at 2 V with the programmed pulse duration followed, after 65 ms, by a second pulse with an amplitude of 2.5 V and a pulse width of 1 ms; if the first pacing is effective, there is no ventricular capture on the second pacing (refractory period); the amplitude of the polarization is deduced at this step. The calibration phase ends during one of the 4 daily measurements (not for the automatic threshold measurement during an interrogation, thus not visible on this tracing) by a search for ventricular fusion over 2 cycles. If the device suspects a fusion, the calibration phase is subsequently repeated with an AV delay shortened to 65 ms to avoid fusion while searching for the threshold. If, despite this setting, a fusion is still detected, the calibration test is stopped and the ventricular voltage is forced to 5 V for the next six hours.

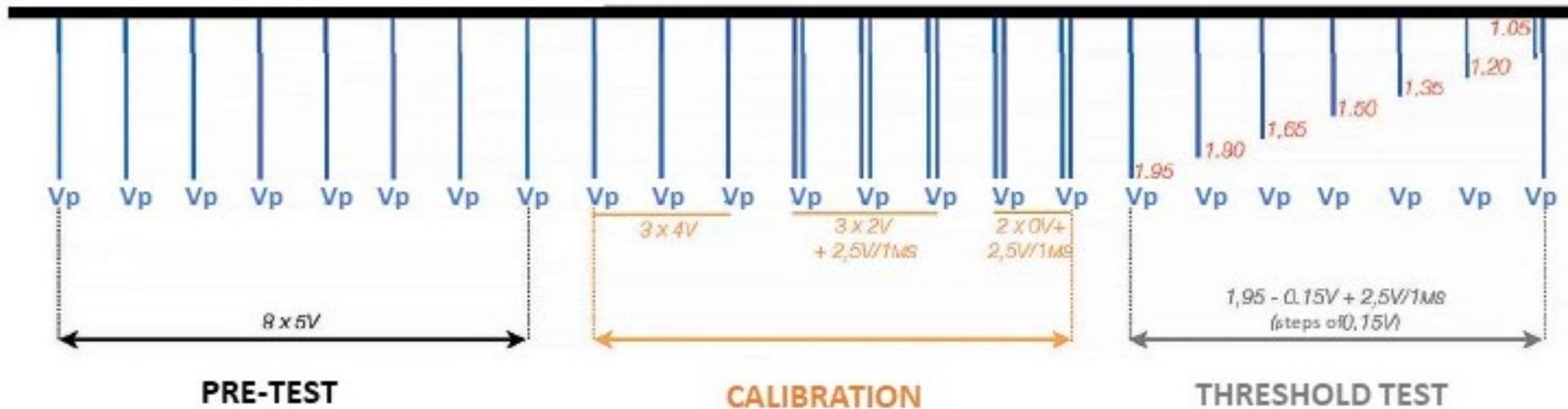


COMMENTS (CONTINUED)

When the calibration phase is completed with demonstration of i) reproducible measurements of the evoked response with sufficient amplitude, ii) a marked difference between the evoked response amplitude and the polarization amplitude and iii) the absence of fusion, the pacemaker applies the next step. The pacing threshold test begins at a value of 1.95 V (programmed pulse duration) with a 0.15 V or 0.25 V (depending on the model) decrement until loss of capture (minimum value tested: 0.15 V). Each pacing pulse is followed by an evaluation period of 65 ms with search for the presence of the signal corresponding to the evoked response. When a loss of capture is observed (polarization but no evoked response), a ventricular safety pacing is delivered 65 ms later with an amplitude of 2.5 V and a pulse width of 1 ms.

On the AIDA Diagnostics screen, in the PM tab, clicking on the Autothreshold Curves button displays the curve of the mean values of the 4 daily measurements from the Ventricular Autothreshold function. The applied ventricular output voltage is indicated in parallel.

AUTOMATIC THRESHOLD TEST EVERY 6 HOURS



ALIZEA DR 21/Mar/2021 English

Print ECG II Adjust

Pacing/Sensing **Brady** **Remote** **Auto-Implant Detect**

Basic Parameters

Mode: **SafeR (AAI<=>DDD)**

Basic Rate: **60 min-1**

Rest Rate: **60 min-1**

Max Rate: **130 min-1**

Hysteresis: **0 %**

AVD Rest/Exer: **155 ms** | **80 ms**

AVD Paced/Sensed Offset: **65 ms**

Pacing/Sensing

	A	V
Sensitivity	0.6 mV	2.5 mV
Sensing Polarity	Bipolar	Bipolar
Autosensing	Monitor	Monitor
Amplitude	3.5 V	3.5 V
Width	0.35 ms	0.35 ms
Paced Polarity	Bipolar	Bipolar
Autothreshold	Off	Auto
Amplitude Safety Margin		x2.0
Min Amplitude		2.5 V
Safety Amplitude		3.5 V
Max Amplitude		5.0 V
Max Rate		100 min-1
Start Time		every 6h
Lead Polarity Switch	On	On

Preprogrammed Settings

Erase Save

Name:

Interro. Overview SmartCheck **Diagnos. AIDA** Param. Tests EGM Report Patient Prog. End

Example of programmeable settings on a new platform (ALIZEA);

Autothreshold: Auto-Monitor-OFF
 Amplitude safety margin: x1.5-x2-x2.5-x3
 Minimum amplitude (V): 1.5-2-2.5-3-3.5 2
 Safety amplitude (V): 2-2.5-3-3.5-4-4.5-5-6

Non programmable parameters

Max amplitude (V): 5
 Max rate (min-1): 100
 Start time: 00:00am, 6:00am, 12:00pm and 6:00pm

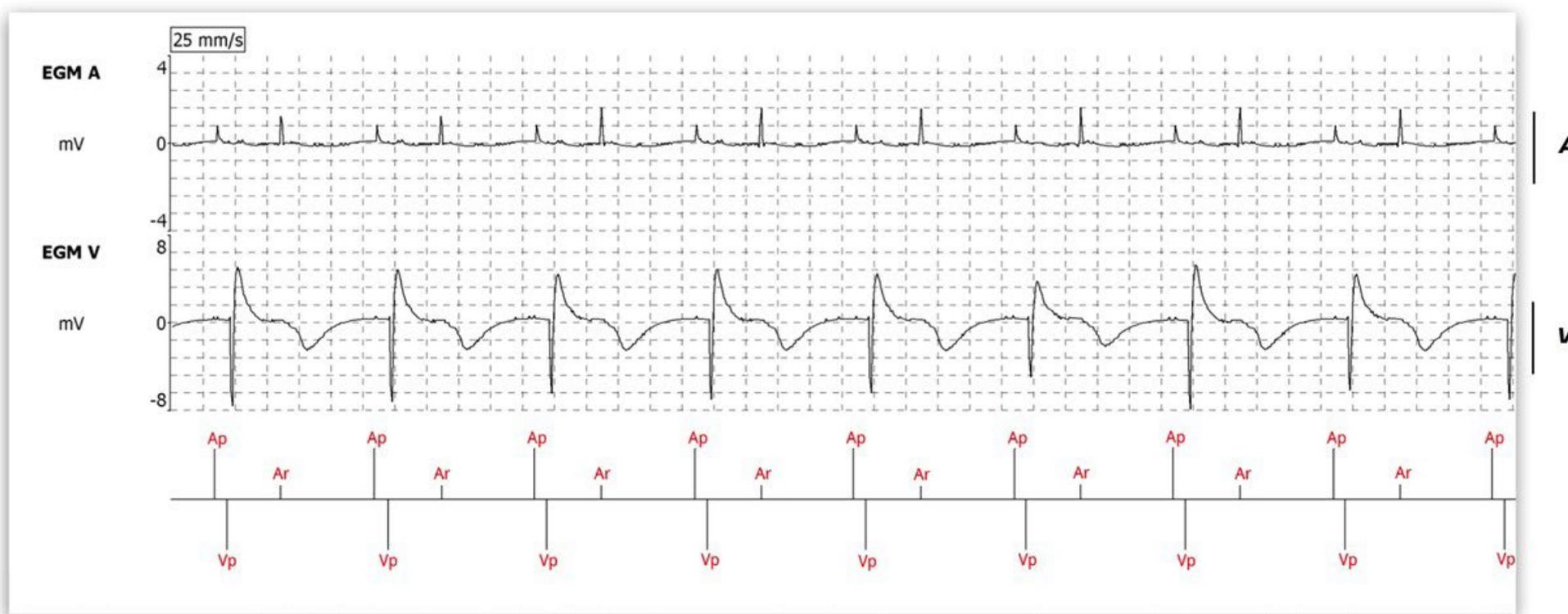
Patient

68-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. there is atrial undersensing
- B. there is loss of atrial capture
- C. there is a pacemaker-mediated tachycardia
- D. there is retrograde conduction
- E. the atrial activity is sensed in the WARAD



TRACING

Repetition of Ap-Vp-Ar cycles; probable absence of atrial capture, effective ventricular pacing with retrograde conduction detected in the WARAD (hence r) and not triggering an AV delay (absence of PMT); suspicion of atrial arrhythmia by the device and AV pacing with AV delay shortened to 30 ms; this sequence lasts long the fallback criterion is never fulfilled;

COMMENTS

This tracing highlights an absence of atrial capture in a patient with sinus dysfunction leading to the repetition of ineffective atrial pacing sequences with retrograde conduction. The specific operation of MicroPort™ pacemakers (WARAD and absence of PVARP following ventricular pacing) allows avoid the occurrence of a PMT despite a relatively long retrograde conduction time. The atrial amplitude was programmed in this patient at 2.5 volts for a pulse duration of 0.35 ms. Without obvious identifiable cause (no lead displacement, no metabolic disorder), the pacing threshold had passed beyond this value (threshold at 3.5 volts for 0.35 ms). Sensing remained appropriate (2 mV) along with normal pacing impedance (630 ohms). A temporary increase in output amplitude to 4.5 Volts for 0.35 ms solved the problem.

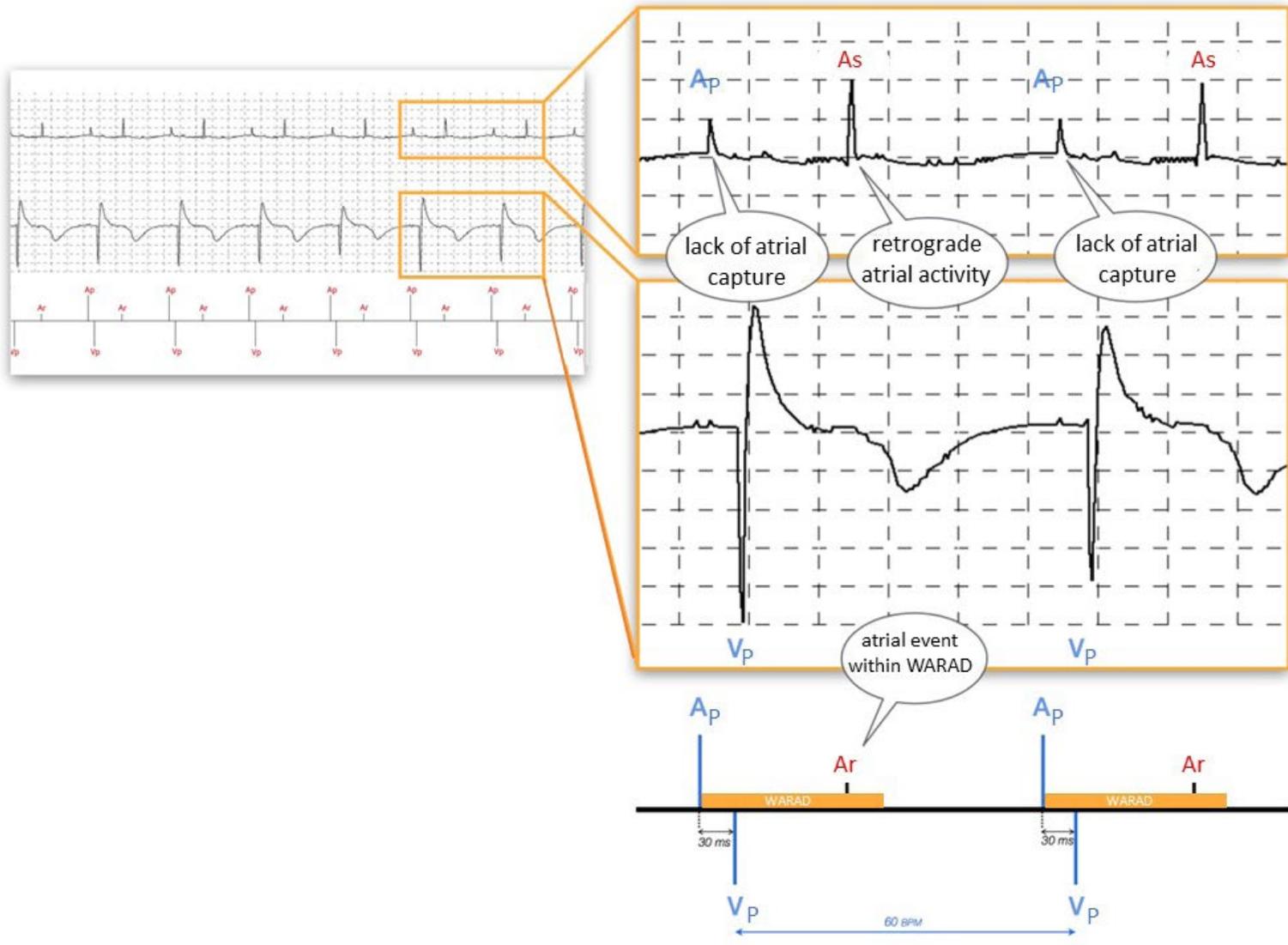
Atrial Autothreshold is available on the latest MicroPort™ pacemaker platforms. Its operation is based on 3 main principles: 1) the atrial pacing threshold test is performed once daily, at night (1 a.m. or 2 a.m. depending on the platform); 2) in the newest platforms, the atrial pacing amplitude is automatically adjusted for the next 24 hours to the atrial pacing threshold x 2 (programmable). There are 2 methods to measure the pacing threshold (PR or AR) chosen by the device according to the presence of a stable sinus rhythm ≥ 50 bpm (threshold achieved with increment of the pacing amplitude) or 1:1 atrioventricular conduction with stable AR intervals (threshold achieved with decrement of the pacing amplitude); 3) the atrial pacing

amplitude is automatically adjusted for the next 24 hours to a value greater than 1 V relative to the measured threshold or the value of the programmed atrial pacing (highest value between the 2);

The threshold test is performed at night in order to promote the presence of a stable rhythm without rate response functioning or other algorithm forcing atrial pacing.

Absence of capture is suggested in the presence of persistent intrinsic atrial activity; the presence of an effective atrial capture is suggested upon disappearance of intrinsic atrial activation; if there is marked sinus dysfunction with preserved atrioventricular conduction, the presence or absence of atrial capture is assessed relative to the presence of 1:1 ventricular conduction; in patients with complete AV block and major sinus dysfunction, the automatic atrial threshold test cannot be performed;

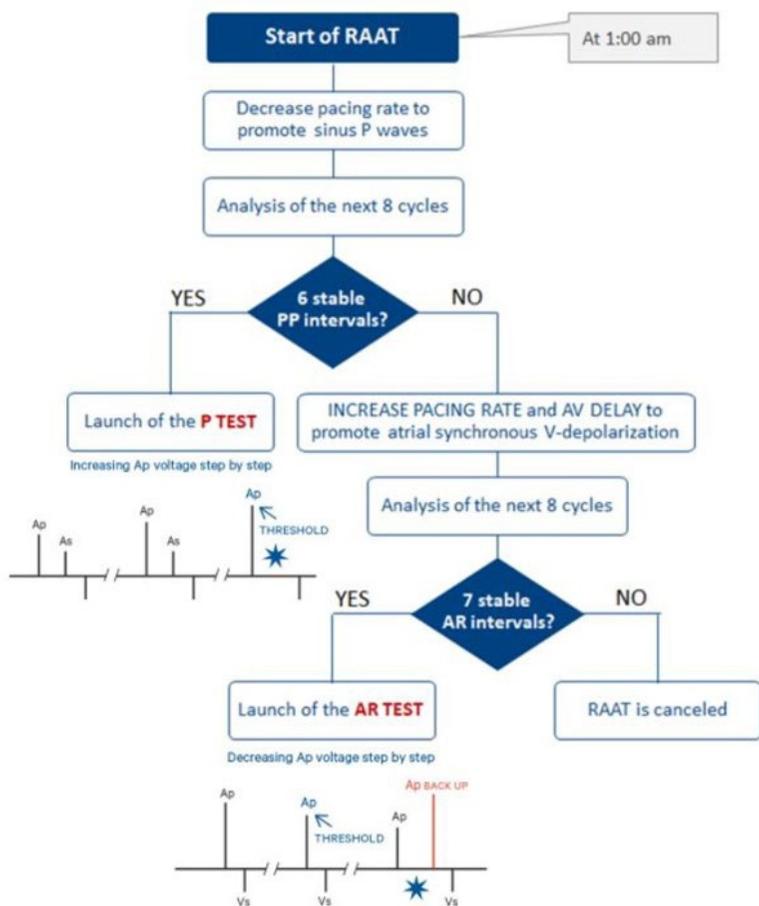
In practice, atrial autothreshold is programmable with the SafeR(R), DDD(R), Dplus(R), SafeR/DDIR, Dplus/DDIR, DDD/DDIR modes. This function is not programmable with the AAI pacing mode or if the programmed basic rate is ≥ 80 bpm. The Atrial Autothreshold function is disabled if the programmed atrial pulse width is greater than 0.50 ms.



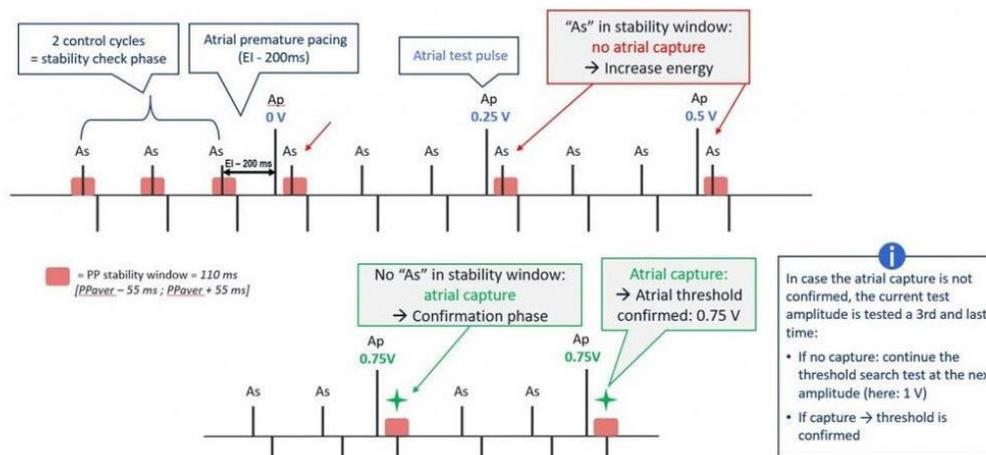
Tracing 30: Atrial capture failure

TRACING

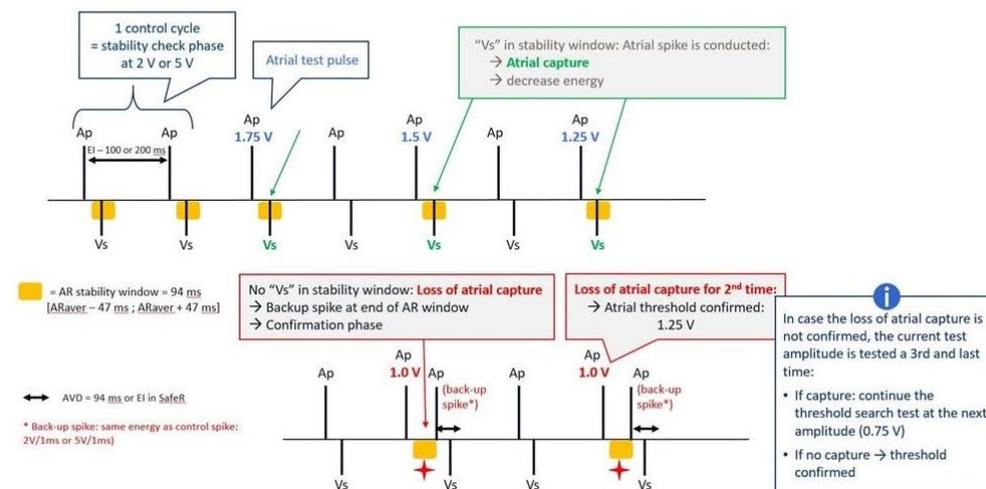
Same patient in AAI mode; atrial pacing (A) and atrial sensing (P); absence of atrial capture; intrinsic atrial activity followed by physiological ventricular activation;

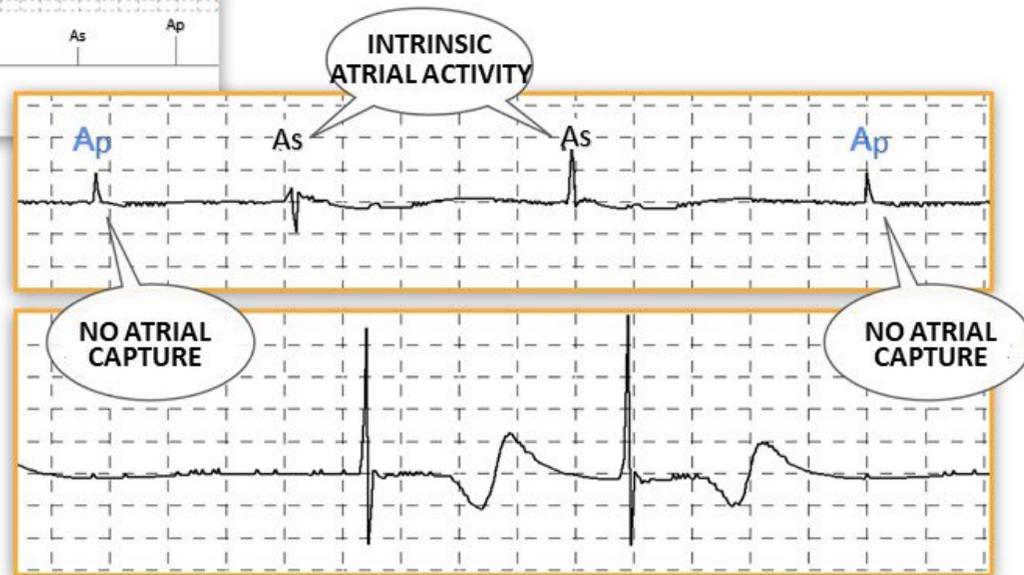


P TEST



AR TEST

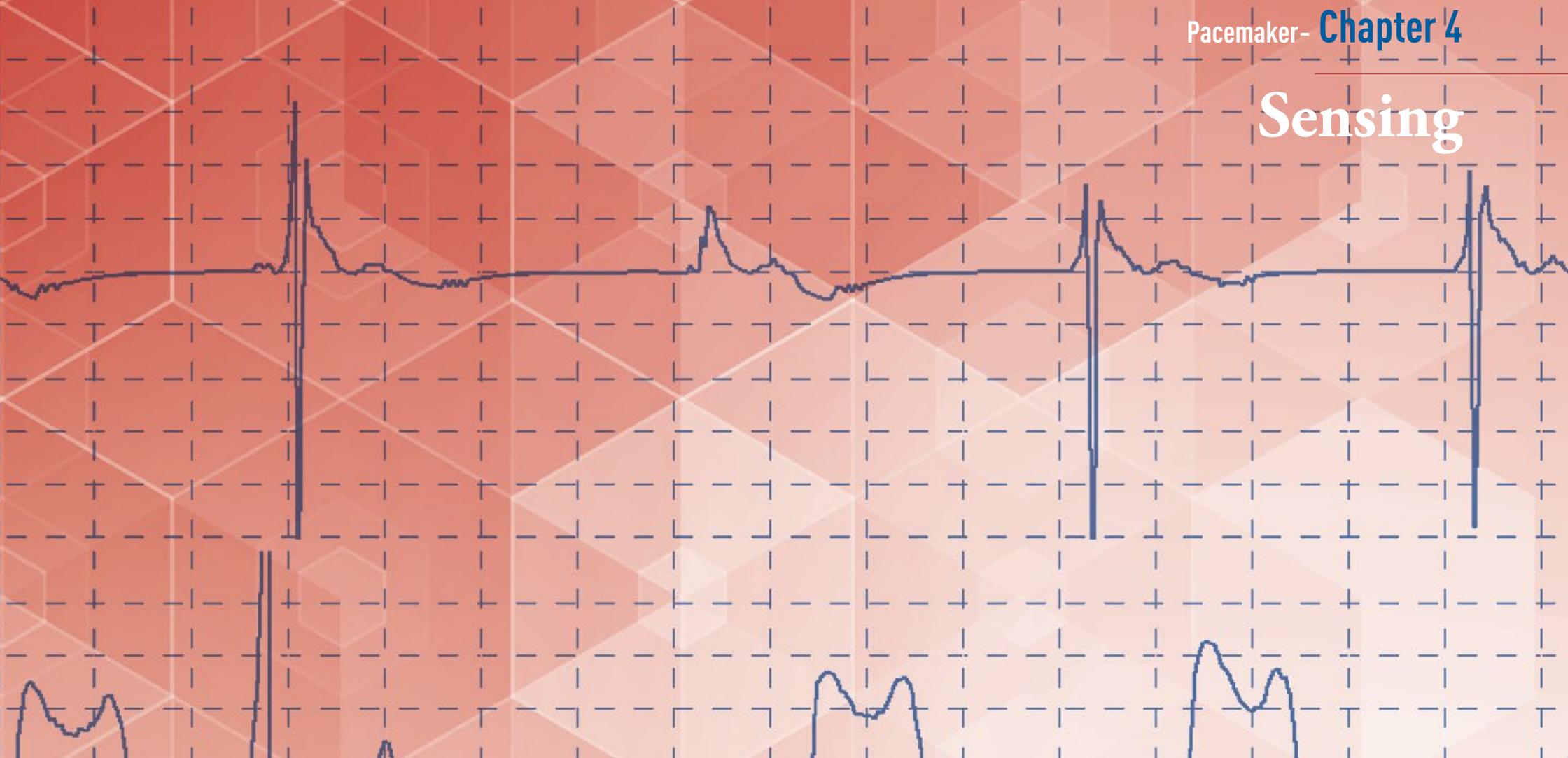






Pacemaker- **Chapter 4**

Sensing



Patient

63-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR programming mode; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the pacemaker switches according to AVB II criterion
- B. the pacemaker switches according to AVB III criterion
- C. there are ventricular sensing failures
- D. there are atrial sensing failures
- E. there are ventricular complexes in the post-atrial blanking period



TRACING

This tracing shows a mode switch according to a second-degree AV block (AVB II) criterion; at the beginning of the tracing, atrial sensing and ventricular sensing; atrial sensing failure followed by rate responsive atrial pacing (probable absence of capture since in the refractory period and absence of change in intrinsic atrial rate); the QRS complex following the unsensed intrinsic atrial activity occurs during the post-atrial ventricular blanking and is therefore not detected (blocked pseudo-atrial event); after 3 identical repetitions, diagnosis of second-degree AV block and switching to DDD mode (vertical line);

COMMENTS

This tracing reveals an intermittent atrial undersensing responsible for mode switches according to a second-degree AV block criterion (QRS complexes not detected because occurring during post-atrial ventricular blanking). The amplitude of the sensed atrial signal may vary depending on the position of the patient and the respiratory cycle. Atrial undersensing may have a pro-arrhythmogenic effect if atrial pacing occurs during a vulnerable atrial period with a risk of atrial arrhythmia induction. In a patient with complete atrioventricular block, atrial undersensing may be symptomatic when occurring during exercise with a sudden drop in heart rate. In addition, atrial undersensing can be followed by ineffective atrial pacing since falling in the atrial refractory period, with the risk of retrograde conduction following ventricular pacing due to the prolonged As-Vp delay, and there is a risk of induction of pacemaker-mediated tachycardia (PMT).

When interrogating a MicroPort™ pacemaker, the measured amplitude of the sensed events are presented in the form of distribution histograms. The amplitude of the P waves typically features a Gaussian-type distribution for this patient. The pattern of the histograms can be highly suggestive of an undersensing: the histogram appears abrogated by the hatched zone corresponding to the programmed sensitivity.

The quality of the sensing can also be measured on trend curves over the last 24 hours where the accuracy (average value) is approximately 8 minutes per point; for trend curves over the last 6 months, each point represents the average daily sensing value.

In the PM tab of the Diagnostics AIDA screen, selecting the Autosensing magnifier displays the P wave distribution; selecting the P/R Waves button displays the R wave distribution; selecting the Monitor button over the last 24h displays the trend curves of the P and R waves over the last 24 hours.

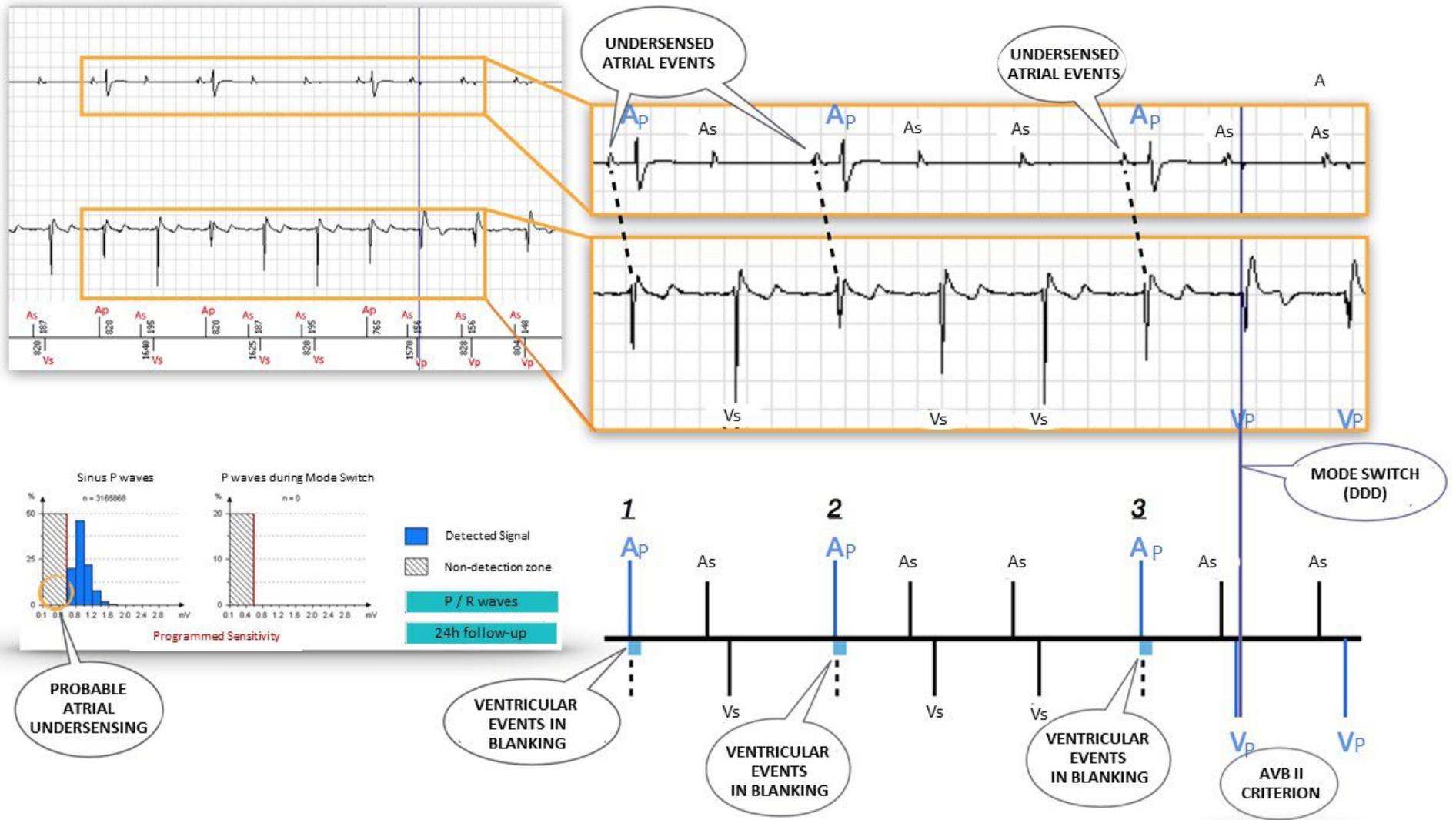
"Sinus" P waves represent P wave sensing outside the WARAD. The "fallback" P waves represent P-wave sensing during the Fallback phase (DDI). P-wave sensing during the suspicion phase is not taken into account.

The PVCs represent R-wave sensing in which the coupling is 25% shorter than the average of the 8 preceding "normal" ventricular cycles.

Note that the measurement period equals the last 2 months.

In the PM tab of the Diagnostics AIDA screen, selecting the Leads Measurements magnifier displays the trend curves of atrial sensing; clicking the V Lead button displays the trend curves of ventricular sensing.

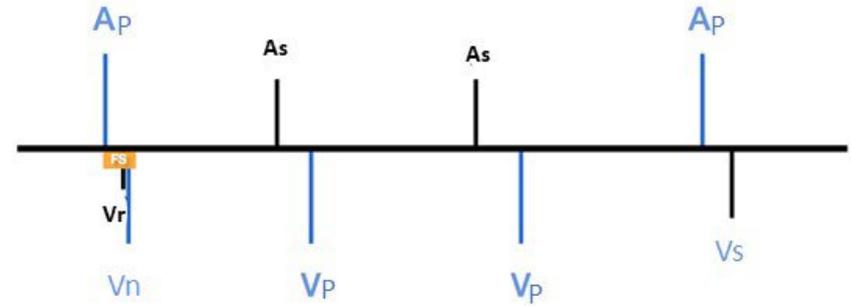
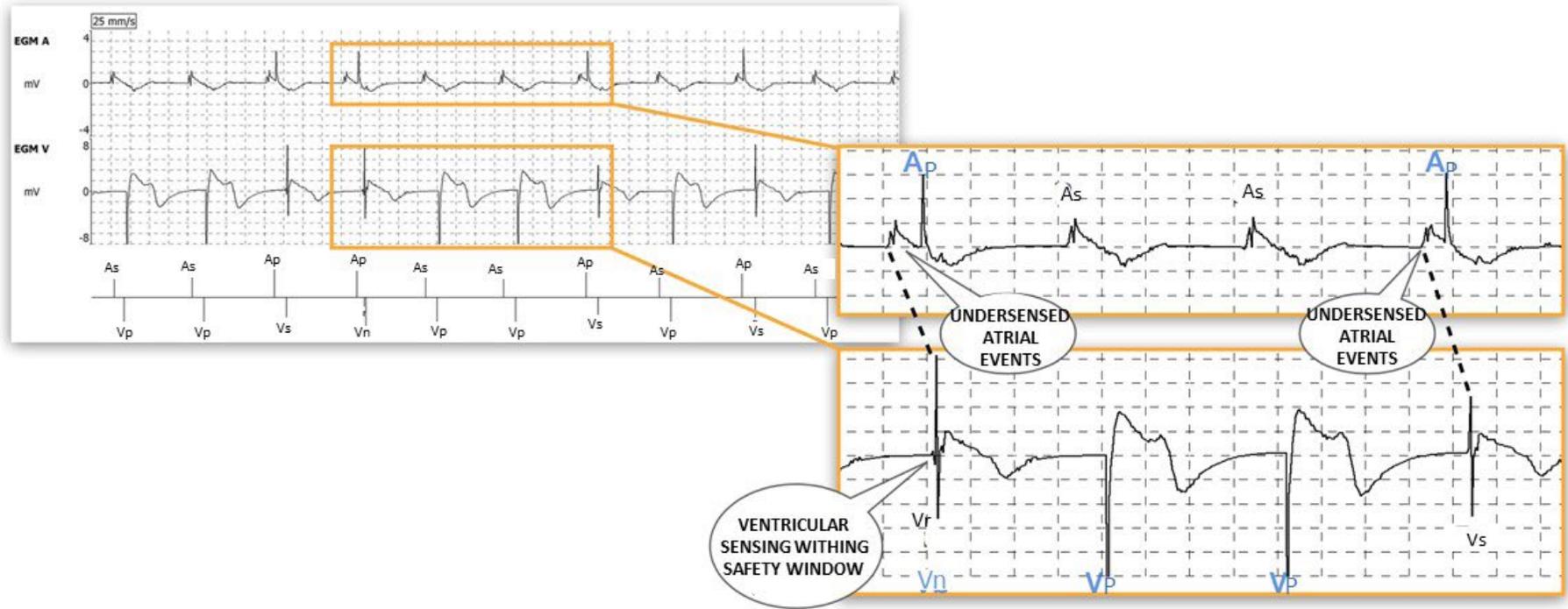
The proper functioning of the SafeR algorithm requires perfect atrial and ventricular sensing as well as atrial pacing. An increase in atrial threshold (absence of atrial capture), an atrial or ventricular undersensing leads to the occurrence of inappropriate switches to DDD mode. The ability to record mode-switching episodes on MicroPort™ pacemakers allows to diagnose such problems even when they are intermittent and rare.



Tracing 32: Atrial sensing failure 2

TRACING

Patient implanted with a Reply DR dual-chamber pacemaker in DDD mode; this tracing shows an atrial sensing failure followed by rate response atrial pacing (probable absence of capture since in the refractory period and absence of change in intrinsic atrial rate); the first QRS complex following the unsensed intrinsic atrial activity occurs in a safety window and is followed by ventricular pacing at the end of the safety window (DDD mode);



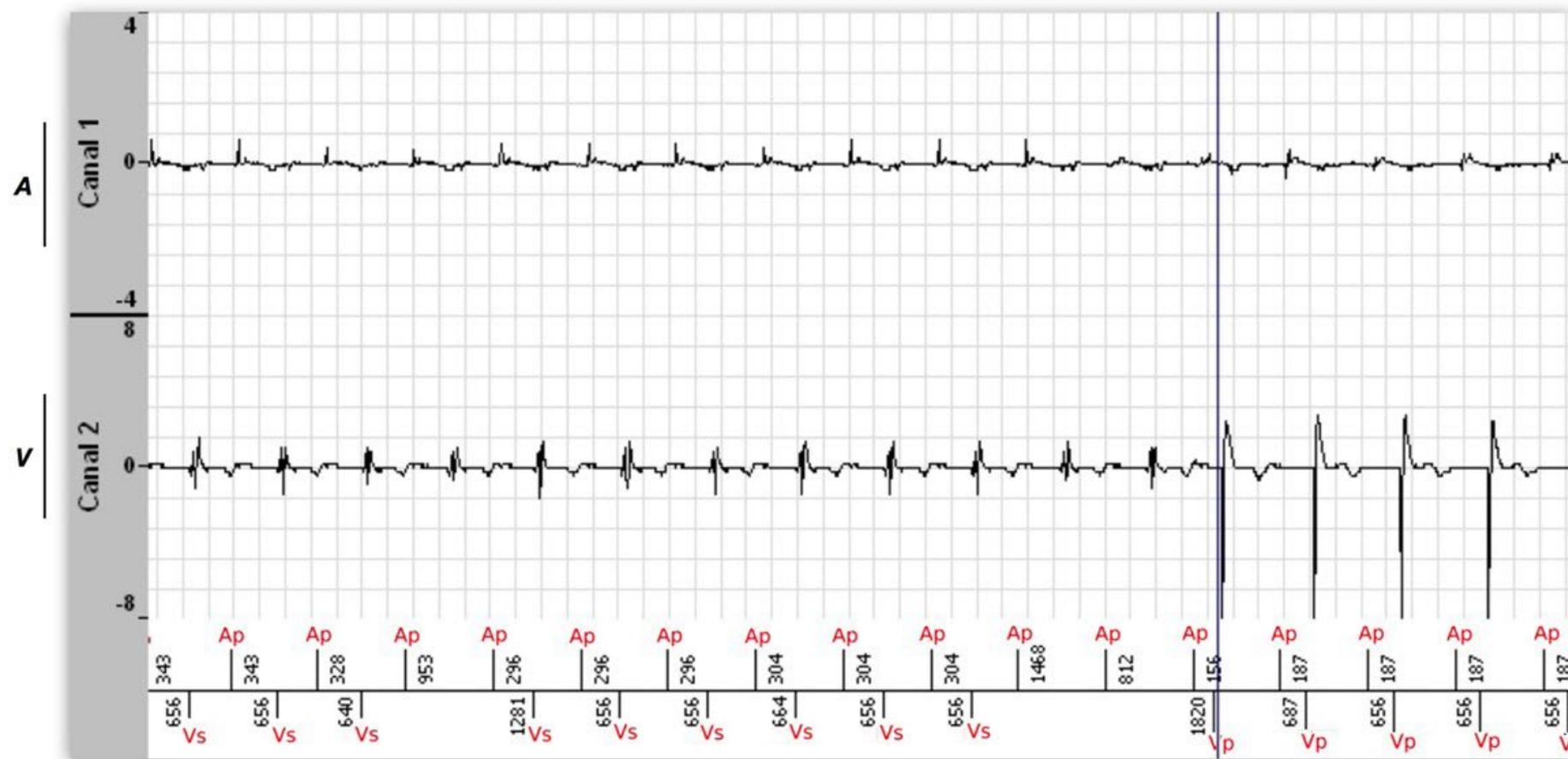
Patient

73-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the pacemaker switches according to AVB III criterion
- B. the pacemaker switches according to ventricular pause criterion
- C. there are ventricular sensing failures
- D. there are atrial capture failures
- E. there are ventricular complexes in the post-atrial blanking period



TRACING

This tracing shows a mode switch according to a third-degree AV block (AVB III) criterion; at the beginning of the tracing, atrial pacing and ventricular sensing; isolated ventricular sensing failure; ventricular sensing failure on 2 consecutive cycles leading to the diagnosis of third-degree AV block by the device and switch to DDD mode (vertical line);

COMMENTS

This tracing shows an example of inappropriate switching in the context of ventricular undersensing and demonstrates the interest of viewing all the tracings recorded in the device memory, allowing sometimes to make unexpected diagnoses. Once again, the pattern of the histogram with abrogation of part of the Gaussian curve by the programmed sensitivity value highly suggests of ventricular undersensing.

Proper programming of the sensitivity level should enable to sense of all intrinsic cardiac events occurring in the implanted chamber while not sensing other events (crosstalk with sensing of cardiac signals from the other chamber, myopotentials, interferences, etc). Programming bipolar sensing increases the specificity of detection compared to unipolar sensing by limiting the risk of sensing extracardiac or crosstalk signals and allows the programming of high sensitivity values (0.3 at 0.5 mV in the atrium, 2 to 3 mV in the ventricle). On the other hand, in unipolar configuration, the risk of crosstalk or the sensing of extracardiac signals forces the programming of lower sensitivity levels (1 to 1.5 mV in the atrium and 4 to 5 mV in the ventricle) with an increased risk of undersensing.

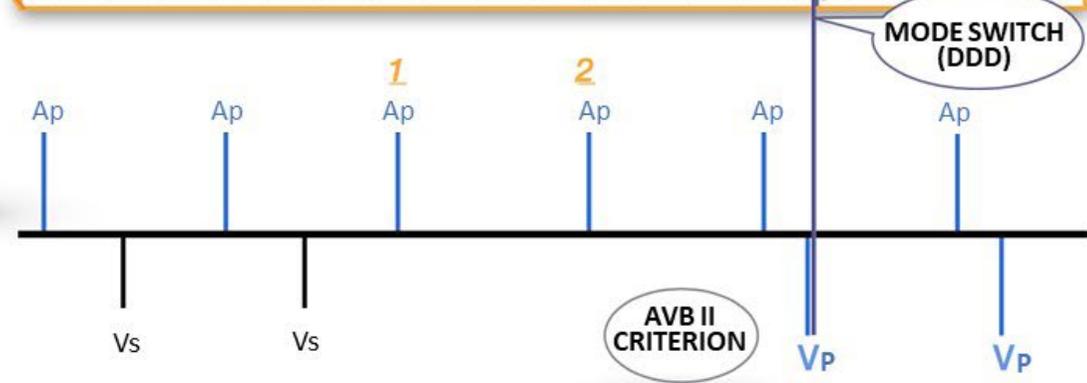
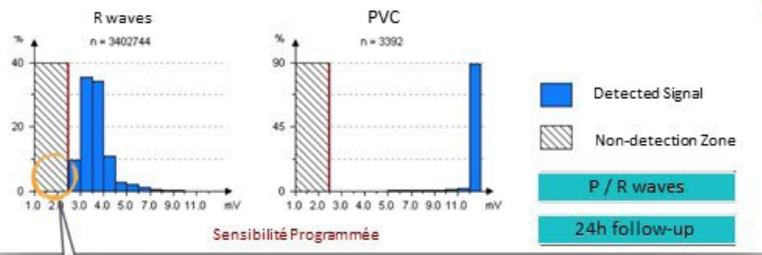
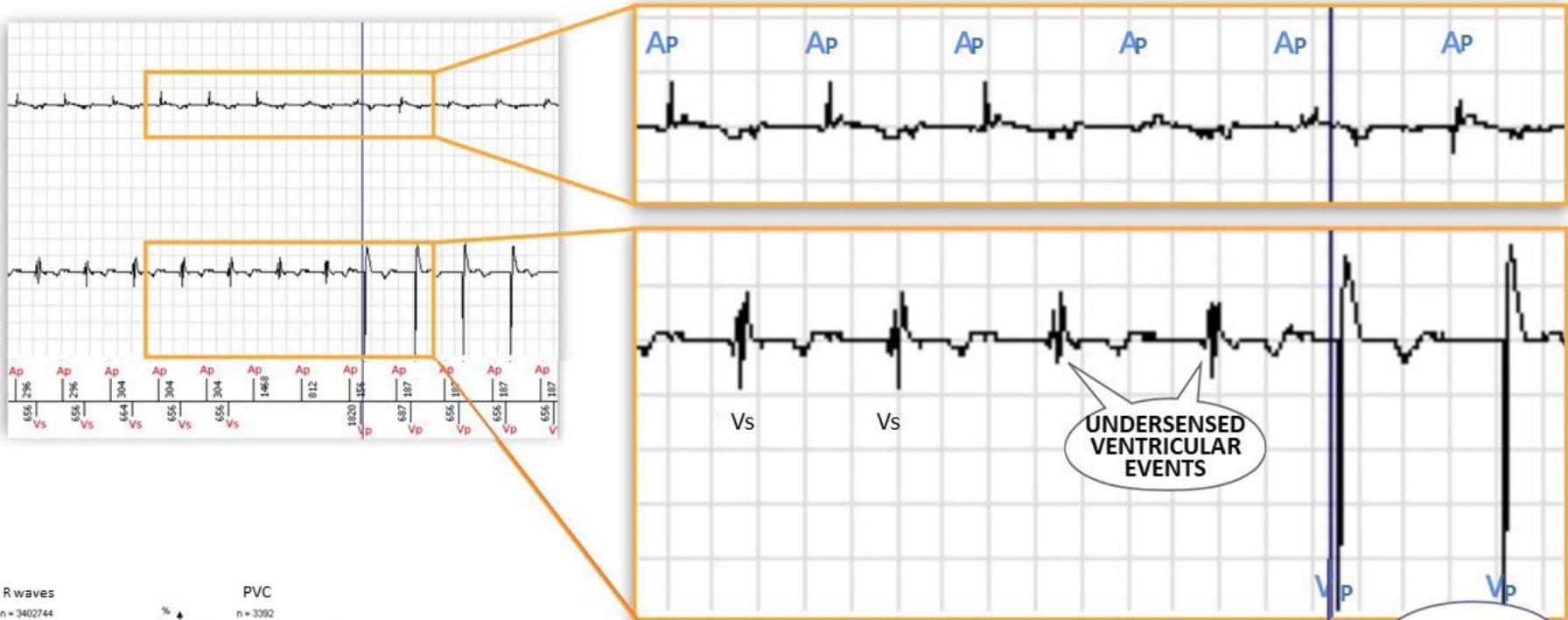
Traditionally, unlike defibrillators, pacemakers function with a stable, fixed sensitivity throughout the cardiac cycle. Increasingly, even if the sensing constraints are not the same (critical need for a defibrillator to sense and treat very fast, polymorphic, low-voltage ventricular rhythm disorders), modern pacemakers from other competitors

allow an adaptive sensitivity (sensitivity level varies according to the amplitude of the sensed R wave or P wave) with a progressive increase in sensitivity during the cardiac cycle (possibility of sensing small amplitude signals without oversensing the T wave).

The choice differs for MicroPort™ pacemakers with 2 options: fixed sensitivity or Autosensing function (available for the atrial channel and the ventricular channel). The Autosensing function does not correspond to the sensing method used in implantable defibrillators of the same manufacturer in pacemakers. When autosensing is programmed, the amplitude of the atrial and ventricular events are monitored continuously with automatic cycle-to-cycle adjustment of the sensitivities. The amplitude of the signals is averaged over 8 consecutive cycles and the sensitivity is programmed at about one-third (37.5%) of this average value. The level of sensitivity can therefore change from one cycle to another although remains fixed within each cycle (no gradual increase in sensitivity during the cycle to obtain a maximum value at the end of diastole as in a defibrillator).

Following a premature atrial contraction, an atrial arrhythmia or atrial pacing, atrial sensitivity is forced to 0.4 mV. Atrial Autosensing applies a sensitivity ranging from 0.4 mV to 3 mV.

The Autosensing function is available on both channels and allows to measure the amplitude of the sensed signals (MONITOR programming) and automatic adjustment of the sensitivity (AUTO programming) by averaging the amplitude of 8 consecutive cycles. This sensitivity adjustment method therefore differs from that used in implantable defibrillators.



COMMENTS (CONTINUED)

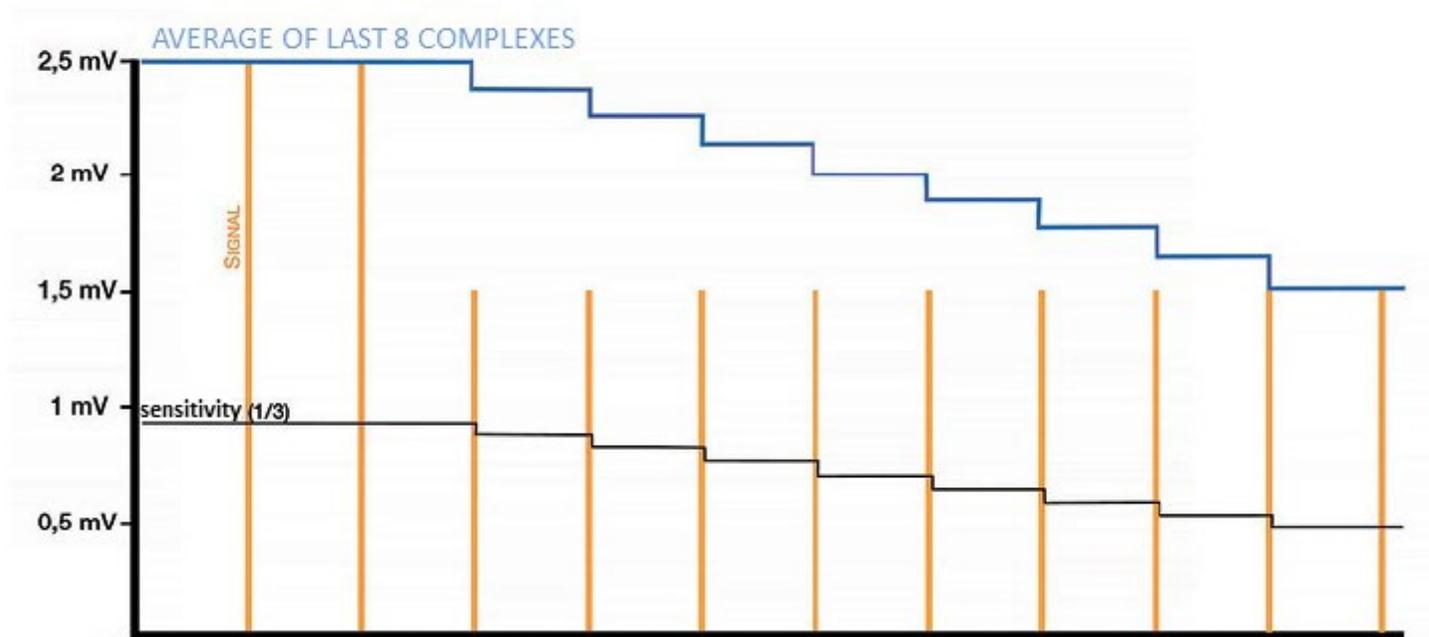
Similarly, following ventricular pacing, ventricular sensitivity is forced to 1.5 mV in unipolar mode and 2.5 mV in bipolar mode. Ventricular Autosensing applies a sensitivity ranging from 1.5 mV (unipolar) or 2.5 mV (bipolar) to 6 mV.

It is therefore possible to program Autosensing to:

- MONITOR allows to measure the amplitudes of the P waves (sinus and pathological) and the R waves (normal and PVC) without automatic adjustment of the sensitivity settings: it remains fixed

- AUTO allows to measure the amplitudes of the P waves and the R waves with automatic adjustment of the sensitivities as previously described

There are a number of restrictions: Atrial Autosensing is programmable on AUTO if the atrial sensing sensitivity is bipolar (if unipolar, only Monitor mode is available) and if the AV delay is longer than 65 ms.



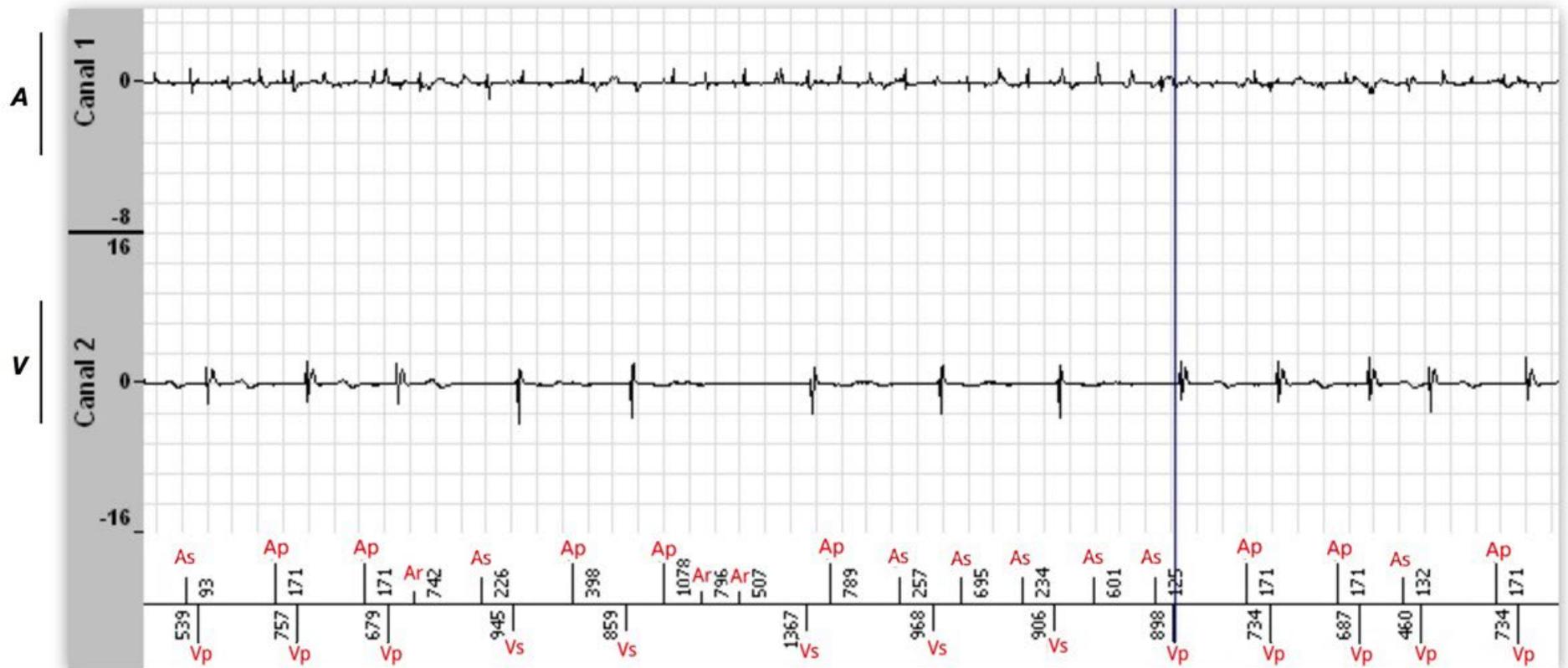
Patient

73-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the pacemaker switches according to AVB II criterion
- B. the pacemaker switches according to AVB III criterion
- C. there is an undersensed atrial fibrillation
- D. there are ventricular sensing failures
- E. there is an increase of the atrial pacing threshold



TRACING

This tracing shows a mode switch according to a second-degree AV block (AVB II) criterion; the analysis of the atrial EGM reveals the presence of fast, irregular signals with variable morphology intermittently detected by the device; it is therefore an intermittent detection of atrial fibrillation leading to absence of fallback; rate responsive atrial pacing is undersensed; diagnosis of second-degree AV block by the pacemaker when at least 3 non-conducted Ap or As complexes (atrial sensing outside the WARAD) out of 12 are highlighted, and subsequent switch to DDD mode (vertical line);

COMMENTS

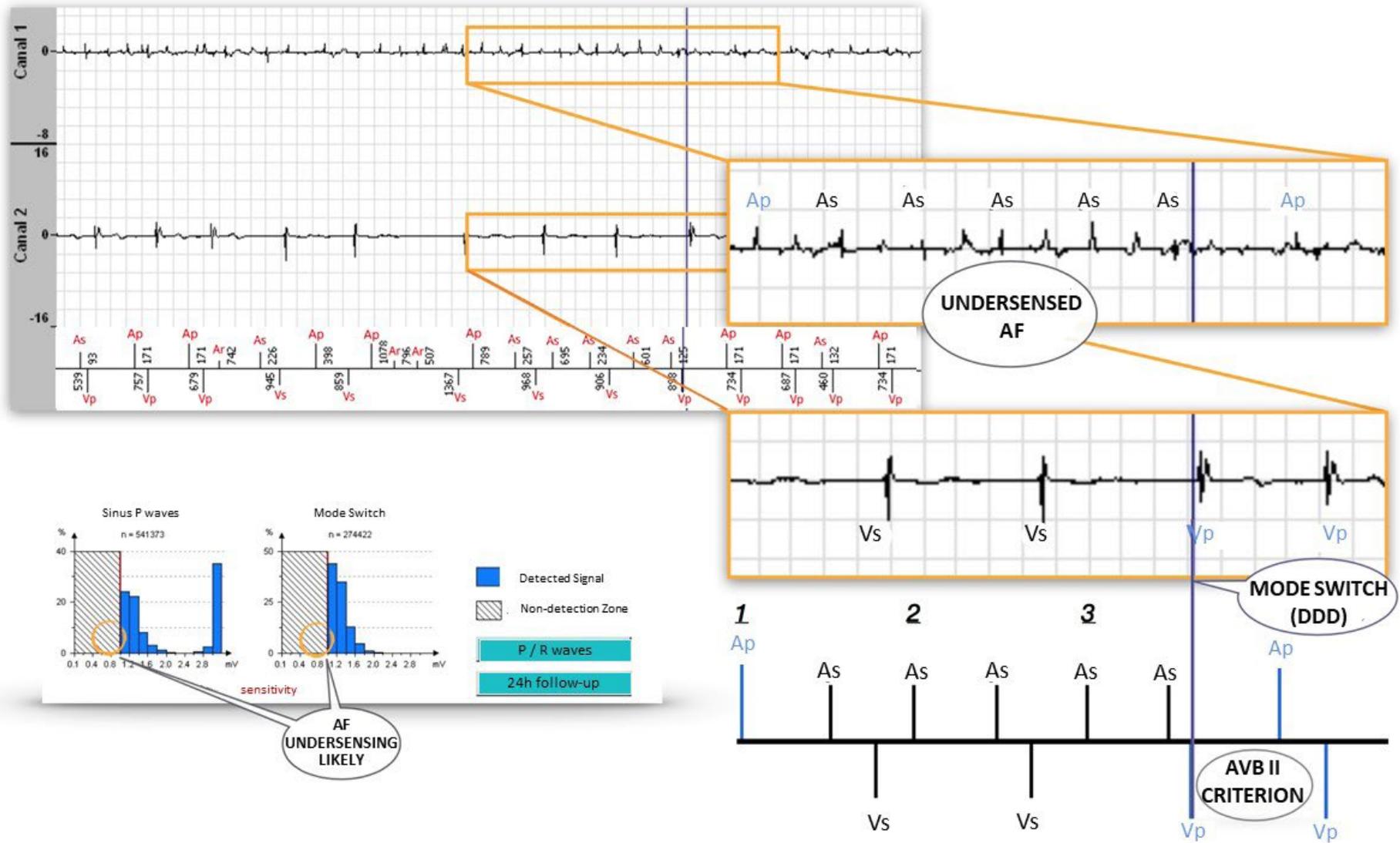
This tracing reveals atrial sensing failure during an episode of AF leading to a false diagnosis of atrioventricular block, inappropriate switching to DDD mode and a moderate increase in the percentage of ventricular pacing. This example illustrates the need to verify the EGM and marker chains recorded by the device and to deeply analyse the provided information. Indeed, in this patient, the AF load was falsely low, the majority of arrhythmia episodes being underdetected. False AF diagnoses are frequent (crosstalk, noise on the atrial lead) in a paced patient, and requires the adjustment of the atrial sensitivity in order to ensure a proper monitoring of the arrhythmias (important to decide the start of anticoagulant therapy or to check the effectiveness of an antiarrhythmic treatment).

The screenshot displays the configuration menu for a pacemaker, with tabs for Pacing/Sensing, Brady, Remote, and Auto Implant Detect. The settings are organized into several sections:

- MRI:** MRI Mode is set to Off.
- Basic Functions:** Smoothing is Off; Mode Switch/Fallback rate is On (60 min-1); Anti-PMT is Reprog.
- Rate Response:** Rate response is No.
- Refractory period:** Post V Atrial Blanking is 150 ms; Post R Atrial Blanking is 95 ms.
- SafeR : AAI=>DDD criteria:** AVB I switch is Rest+Exer; Long PR at rest is 350 ms; Long PR at exercise is 250 ms; Max pause is 3 s.
- Prevention of A arrhythmia:** Overdrive is Off; PAC pause suppression is Off; PAC acceleration is Off.
- Apnea:** Monitoring is Off; Night period is 00:00-05:00.
- Preprogrammed Settings:** Includes buttons for Enable and Save, and a field for Name. The first interrogation date is 06/Feb/2022 14:14.

The two distribution histograms of P-wave amplitude in sinus rhythm and in fallback suggest the presence of undersensing with abrogation of a part of the Gaussian curve corresponding to signals of less than 1 mV (programmed sensitivity). There are 2 subgroups of P wave histograms: on the right, at about 2.8 mV, the P waves are truly sinus; the group on the left has a profile identical to that of the P waves in fallback, and corresponds to AF signals observed outside the refractory periods when the AF is poorly detected. In this patient, a new programming (sensitivity increased by decreasing the programmed value) allowed to achieve a good balance between the sensing of atrial activity in AF and absence of oversensing at the level of the atrial channel.

The analysis of all of tracings recorded in the device memory allows verifying to make unexpected diagnoses on intermittent abnormalities (sensing failures, capture failures, etc).



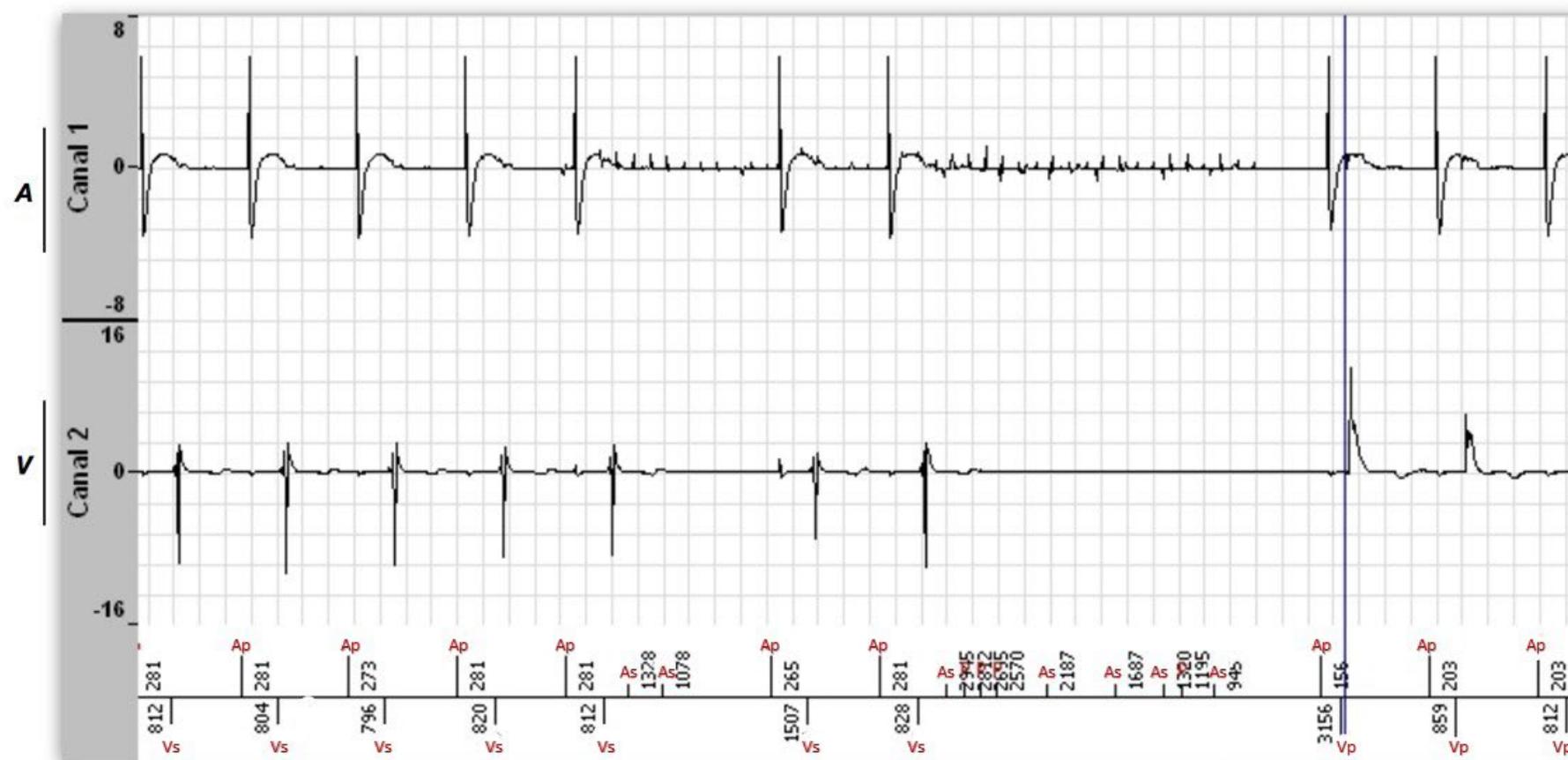
Patient

73-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the pacemaker switches according to an AVB III criterion
- B. the pacemaker switches according to a pause criterion
- C. there is oversensing of noise by the atrial lead
- D. there are ventricular sensing failures
- E. the patient appears to be atrial channel dependent



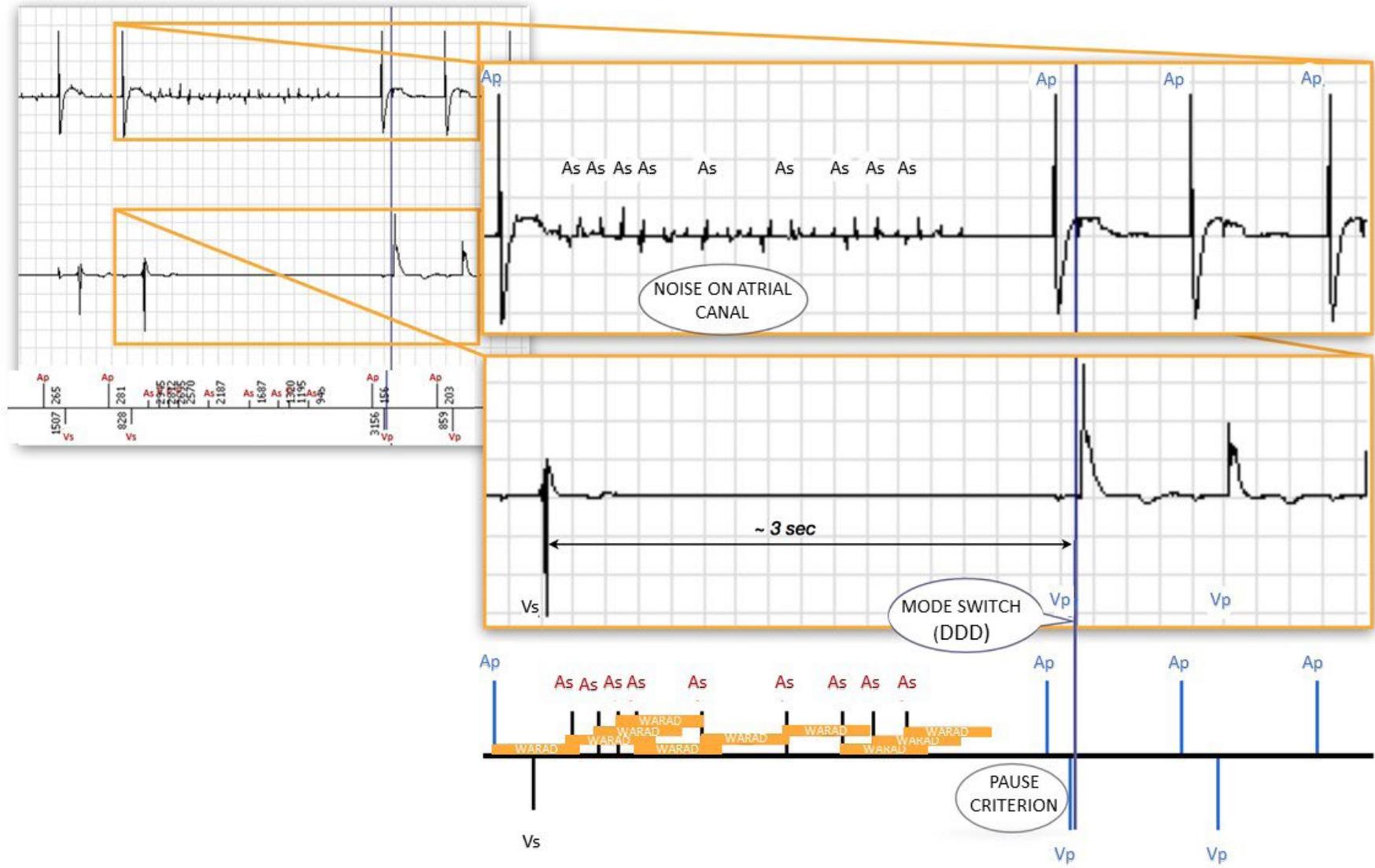
TRACING

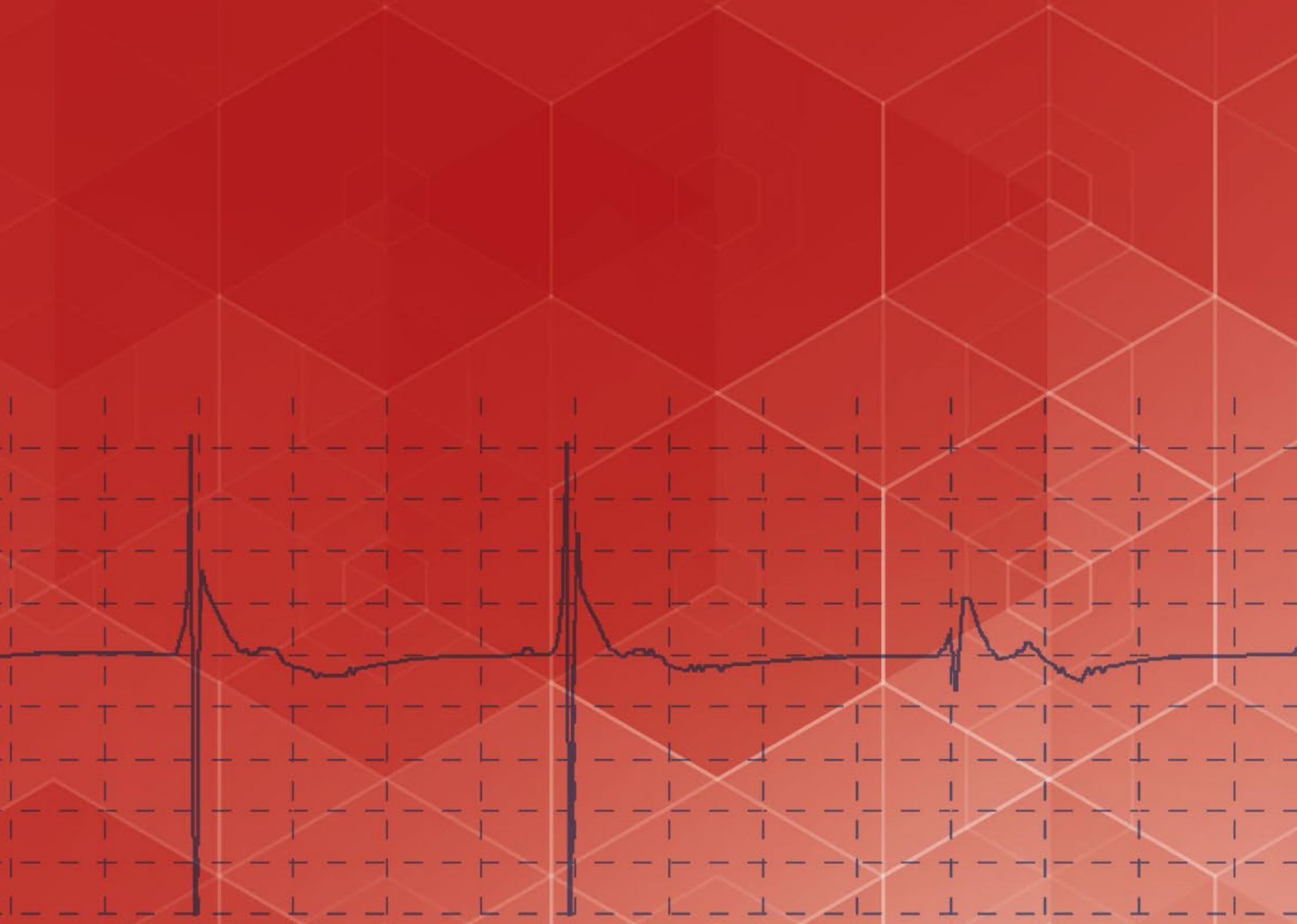
This tracing shows a mode switch according to a pause criterion (> 3 seconds); the tracing initially shows an atrial-paced patient with intrinsic conduction; the analysis of the atrial EGM subsequently shows the presence of fast, irregular signals of variable morphology, appearing as non-physiological; these signals are very fast and are classified as Ar (they do not count as blocked atrial events: no second-degree or third-degree AV block criteria); however, these signals inhibit atrial pacing leading to a ventricular pause (patient with marked sinus dysfunction) and switching to DDD mode (vertical line);

COMMENTS

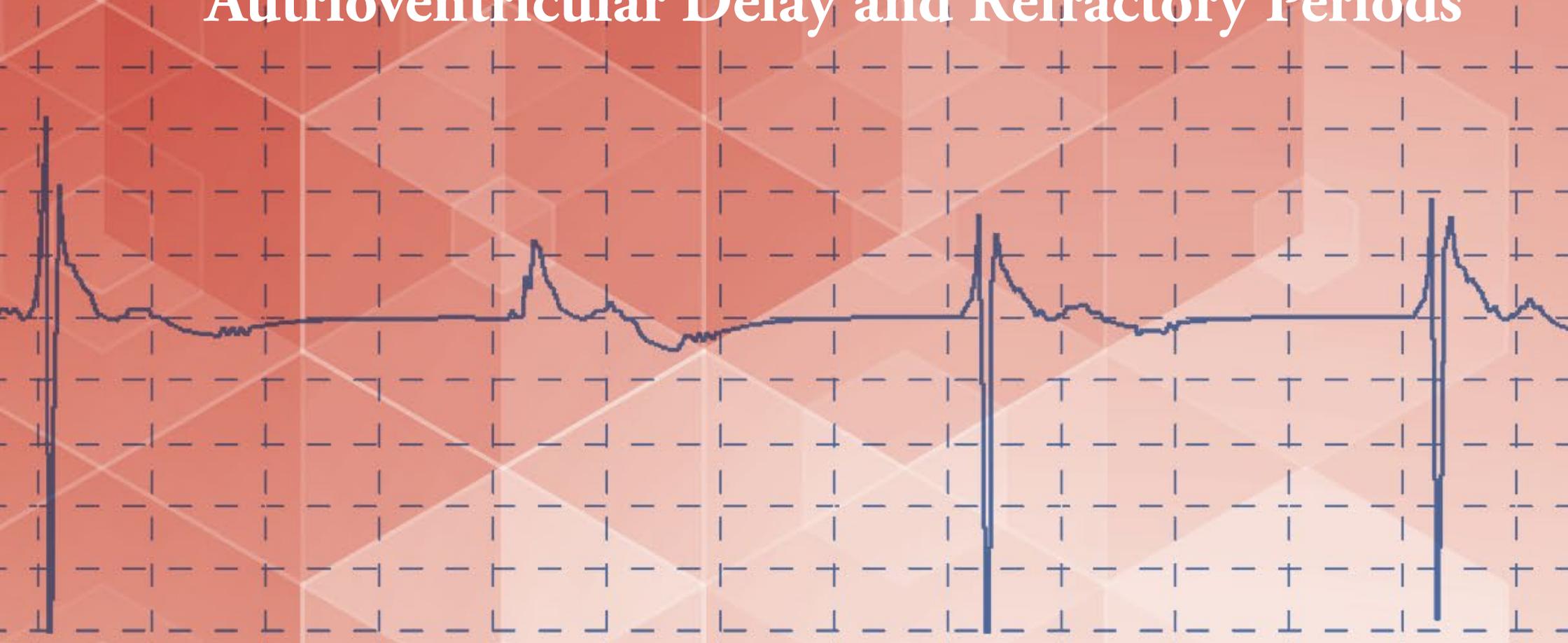
This tracing reveals an oversensing of pectoral myopotentials at the atrial channel level that were reproducible during the in-clinic follow-up by performing counter maneuvers of the arm. The impedance of the atrial lead and the atrial pacing threshold were preserved. A modification of the atrial sensitivity (increase in the programmed value) allowed to solve the problem at least temporarily. The oversensing of myopotentials or a 50 Hz signal can be symptomatic, as in this patient, with a risk of sinus pause in case of oversensing in the atrial channel in a patient implanted for sinus dysfunction or risk of atrioventricular block if oversensing in the ventricular channel.

The event markers and intervals indicate an oversensing of myopotentials: presence of very short atrial cycles which are non-physiological. The oversensing can be observed by various maneuvers: manipulation of the pulse generator, manipulation of the pocket and movement of the ipsilateral arm to reproduce pectoral myopotentials, forced breathing to reproduce diaphragmatic myopotentials. It is essential to systematically verify all the episodes recorded in the device memory: the analysis of the EGMs sometimes allow correct a false diagnosis made by the device.





Atrioventricular Delay and Refractory Periods



Patient

63-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the pacemaker switches according to AVB I criterion
- B. the pacemaker switches according to AVB II criterion
- C. the pacemaker switches according to AVB III criterion
- D. the AV delay on sensed atrial activity is longer than on paced atrial activity
- E. the AV delay on sensed atrial activity is shorter than on paced atrial activity



TRACING

At the beginning of the tracing, pacemaker operating in DDD mode for 100 cycles, then switching to ADI mode; The AVB II criterion fulfilled after 3 in 12 non-consecutive blocked paced atrial complexes: the pacemaker switches back to DDD mode, the AV delay is shorter on intrinsic atrial activity than on paced atrial activity;

COMMENTS

In a dual-chamber pacemaker, the AV delay determines the maximum interval between an atrial event and ventricular pacing. This interval corresponds to the electronic equivalent of the PR interval.

AV delays for paced have different values and sensed atrial events.

Their programming is intended to ensure perfect mechanical coordination between atria and ventricles whether the atrium is sensed or paced. The length of these intervals can be programmed over a wide range, fixed or adaptable and is influenced by a large number of algorithms.

The paced AV delay is applied following atrial pacing when the pacemaker is operating in DDD, DDI, DVI and DOO modes.

The sensed AV delay is applied following a sensed atrial event when the pacemaker is operating in synchronized atrial pacing mode (DDD and VDD).

The optimal sensed AV delay is shorter than the optimal paced AV delay for different reasons:

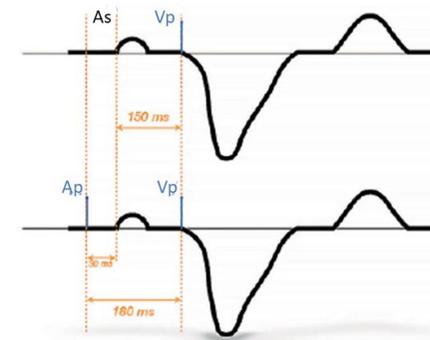
- sensing of the P wave is never performed at the very beginning of the surface P wave, but rather at the passage of the atrial depolarization wave under the electrode. It is often late relative to the onset of the P wave on the surface ECG.
- when the P wave is paced, the conduction time between the right atrium and the left atrium is prolonged.
- the difference between sensed and paced AV delays depends on the position of the lead in the right atrium: on average 30 ms if the lead is positioned in the interatrial septum, 50 ms if in the atrium, 70 ms if in the superior aspect of the right atrial edge and 90 ms if in the inferior lateral aspect. These values represent

averages and therefore the programming should be adjusted to each individual.

- These differences are often longer if there is an intra-and/or interatrial conduction disorder.
- this difference doesn't change so much at exercise, with a tendency to a shortening under the influence of catecholamines which reduces the interatrial conduction time. If there is a major interatrial conductive disorder, this difference may be longer during exercise. In practice, this value can remain fixed throughout the programmed range of rate variation.

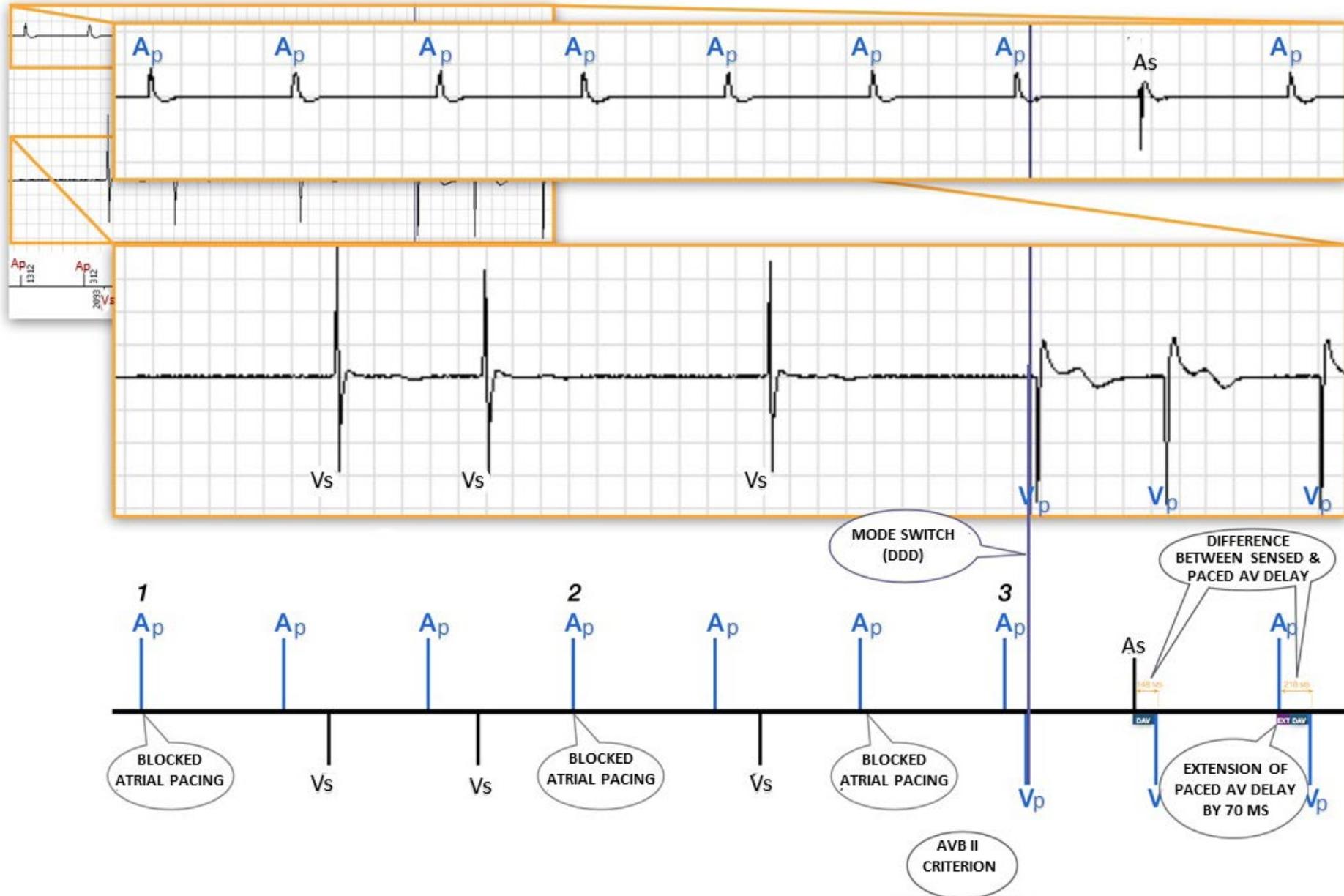
In the present example, $Ap-Vs > Ap-Vp$ since, at this time, the mode is ADI and not DDD.

Physiologically, the PR interval is shortened during exercise, around 4 ms for each 10 beats of rate acceleration. The adaptation of the AV delay is intended to reproduce this physiological phenomenon, and the same variation is applied to the sensed AV delay and the paced AV delay.



The AV delay resulting in optimal hemodynamics varies considerably from one patient to another. An accurate AV delay setting should allow to maintain the temporal relationship between the left atrium and the left ventricle constant and ensure that the left atrial systole is completed before the onset of the left ventricular systole.

Atrioventricular Delay and Refractory Periods



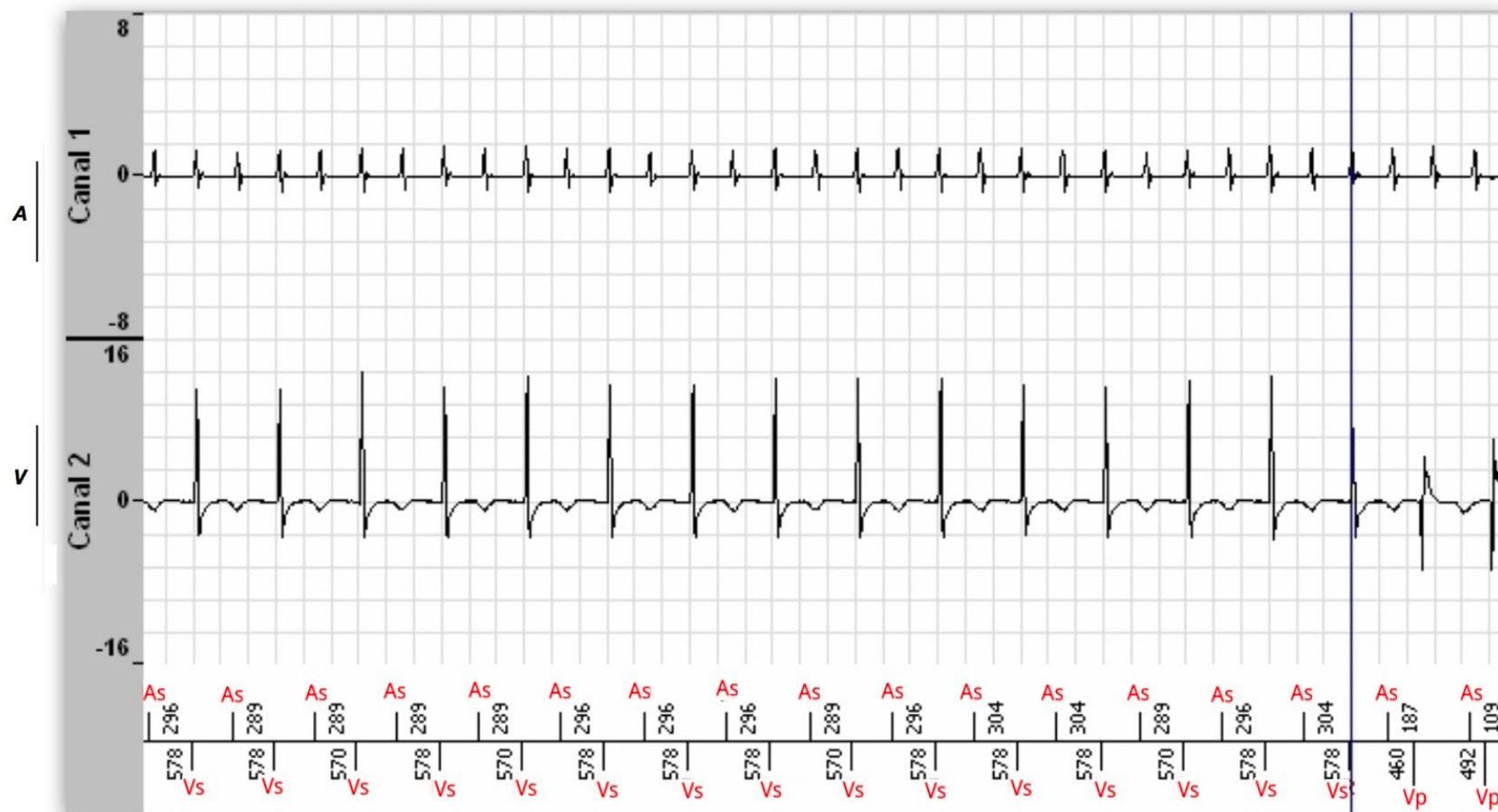
Patient

63-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the pacemaker switches according to AVB I criterion
- B. the pacemaker switches according to AVB II criterion
- C. the pacemaker switches according to AVB III criterion
- D. one in two atrial activities falls in the PVARP
- E. one in two atrial activities falls in the post-ventricular atrial blanking



TRACING

At the beginning of the tracing, the atrial EGM reveals the presence of atrial tachycardia with regular, monomorphic atrial cycles; one out of two signals is sensed by the atrial channel, the second signal falling in the post-ventricular atrial blanking; switching according to an AVB I criterion (vertical line), with the PR interval exceeding the limit value over 6 consecutive cycles; fast ventricular pacing, one in two atrial activities falling in the post-ventricular atrial blanking;

COMMENTS

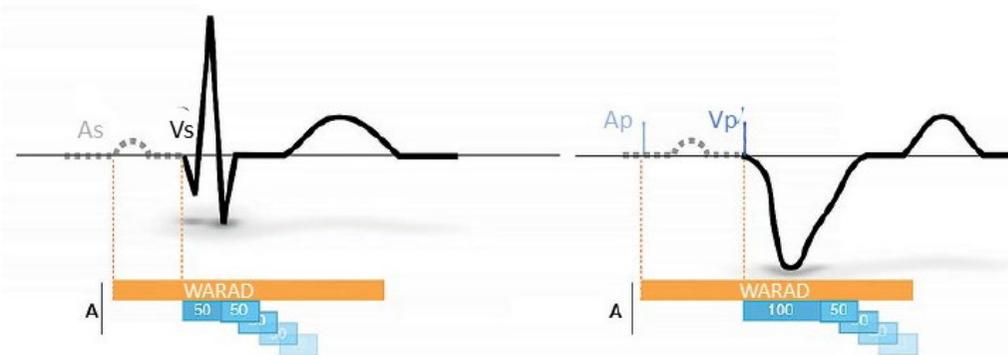
This tracing shows an example of atrial tachycardia misdiagnosed by the device, one in two atrial activities falling in the post-ventricular atrial blanking thus preventing fallback to the DDI mode; however, the pacemaker inappropriately switches to DDD mode when it analyses with a pseudo-pattern of first degree AV block. The problem subsequently persists with rapid ventricular pacing, with one in two atrial activities still in the post-ventricular atrial blanking.

The post-ventricular atrial blanking (PVAB) is an absolute refractory period applied in the atrium after ventricular sensing and pacing.

Its purpose is to prevent the sensing, by the atrial chain, of the ventricular pacing artifact and the depolarization of intrinsic or paced ventricular activity. This blanking is used when the pacemaker is operating in DDD, DDI, VDD and VDI modes.

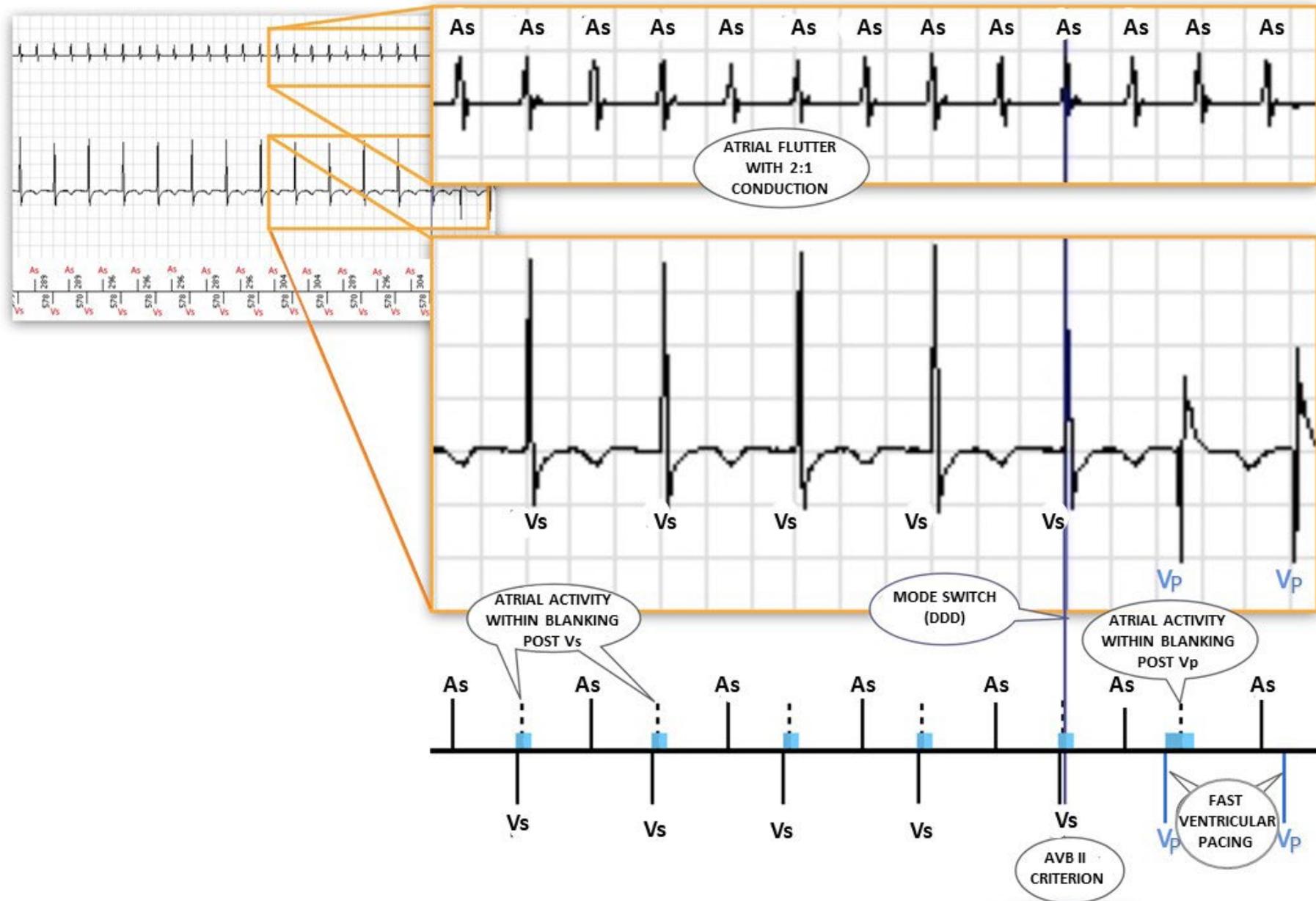
For a MicroPort™ pacemaker, after ventricular pacing, an absolute refractory period of 150 ms (nominal value, programmable) is triggered at the atrial level. The first 100 ms represent an absolute refractory period while the next 50 ms are automatically retriggerable. Following ventricular sensing, an absolute refractory period of 100 ms (nominal value), programmable is triggered at the atrial level. The first 50 ms represent an absolute refractory period while the next 50 ms are automatically retriggerable. When the user modifies the PVAB value (post-pacing), the post-sensed PVAB is also modified. The post-ventricular paced PVAB is the value that is programmed. Since Alizea platform, the 2 periods are programmable independently: "post V atrial blanking" after ventricular pacing and "post R atrial blanking" after ventricular sensing. "Post R atrial blanking" is shorter than "post V atrial blanking".

This tracing shows the limitations of programming an unnecessarily long post-ventricular atrial blanking. Failure to sense one out of two atrial signals during an episode of atrial flutter/tachycardia may lead to the occurrence of poorly-supported paced tachycardia. The combined deleterious effect of the tachycardia and right ventricular pacing can favor symptom onsets. A reduction of the blanking value allows the detection of the second atrial signal (in the WARAD), the diagnosis of atrial arrhythmias and thus rapid switching to an asynchronous mode. To maintain the proper ability to detect atrial arrhythmias and avoid crosstalk, programming must balance blanking periods with atrial sensitivity.



A too long post-ventricular atrial blanking exposes the patient to the risk of non-detection of atrial flutter-tachycardia. In contrast, when the blanking is too short, the risk of crosstalk is increased.

Atrioventricular Delay and Refractory Periods



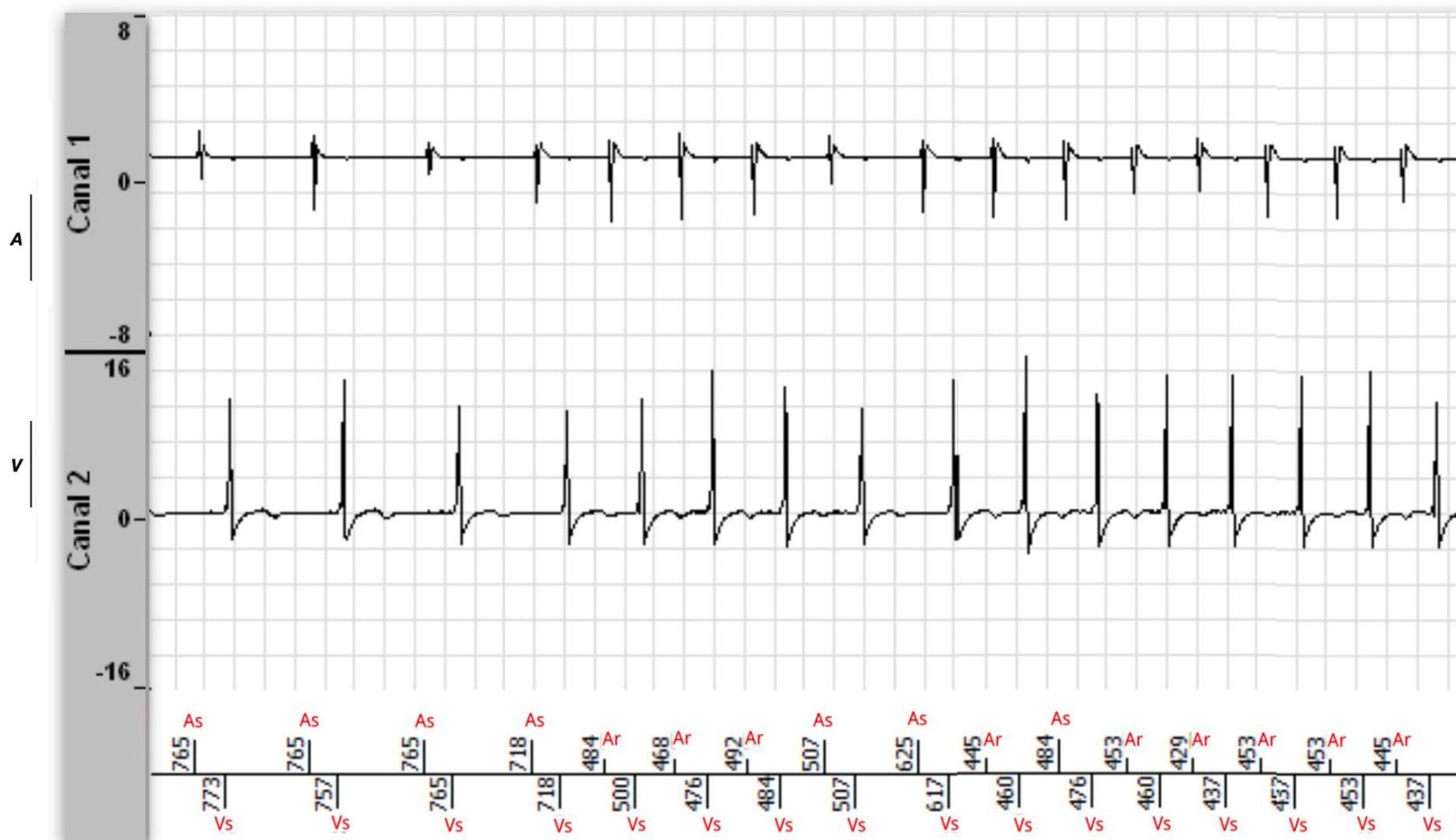
Patient

63-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the Ar marker corresponds to atrial sensing in the PVARP
- B. the Ar marker corresponds to atrial sensing in the post-ventricular atrial blanking
- C. the Ar marker corresponds to atrial sensing in the WARAD
- D. the As marker corresponds to atrial sensing in the WARAD
- E. the As marker corresponds to atrial sensing outside of any refractory period



TRACING

At the beginning of the tracing, sinus rhythm with intrinsic conduction; initiation of atrial arrhythmia by a premature atrial contraction sensed in the WARAD (Ar); the value of the WARAD for the remainder of the episode is fixed on this first cycle; some atrial cycles fall in the WARAD and are classified as Ar, others are outside this refractory period and are classified as As;

COMMENTS

These 2 tracings show the very specific functioning of atrial refractory periods in MicroPort™ dual-chamber pacemakers. Unlike other manufacturers, there is no PVARP after ventricular sensing or pacing. The WARAD is a very specific atrial refractory period triggered by atrial sensing or by atrial pacing. The ARP (Atrial Refractory Period) is an equivalent of PVARP triggered on a premature ventricular contraction.

In DDD mode, following atrial sensing, a refractory period of 80 ms is triggered at the atrial level. The first 30 ms are an absolute refractory period while the next 50 ms are automatically retriggerable upon atrial sensing. The value of this period is not programmable. Following atrial pacing, the periods corresponding to the AV delay + paced/sensed offset are absolute refractory periods at the atrial level.

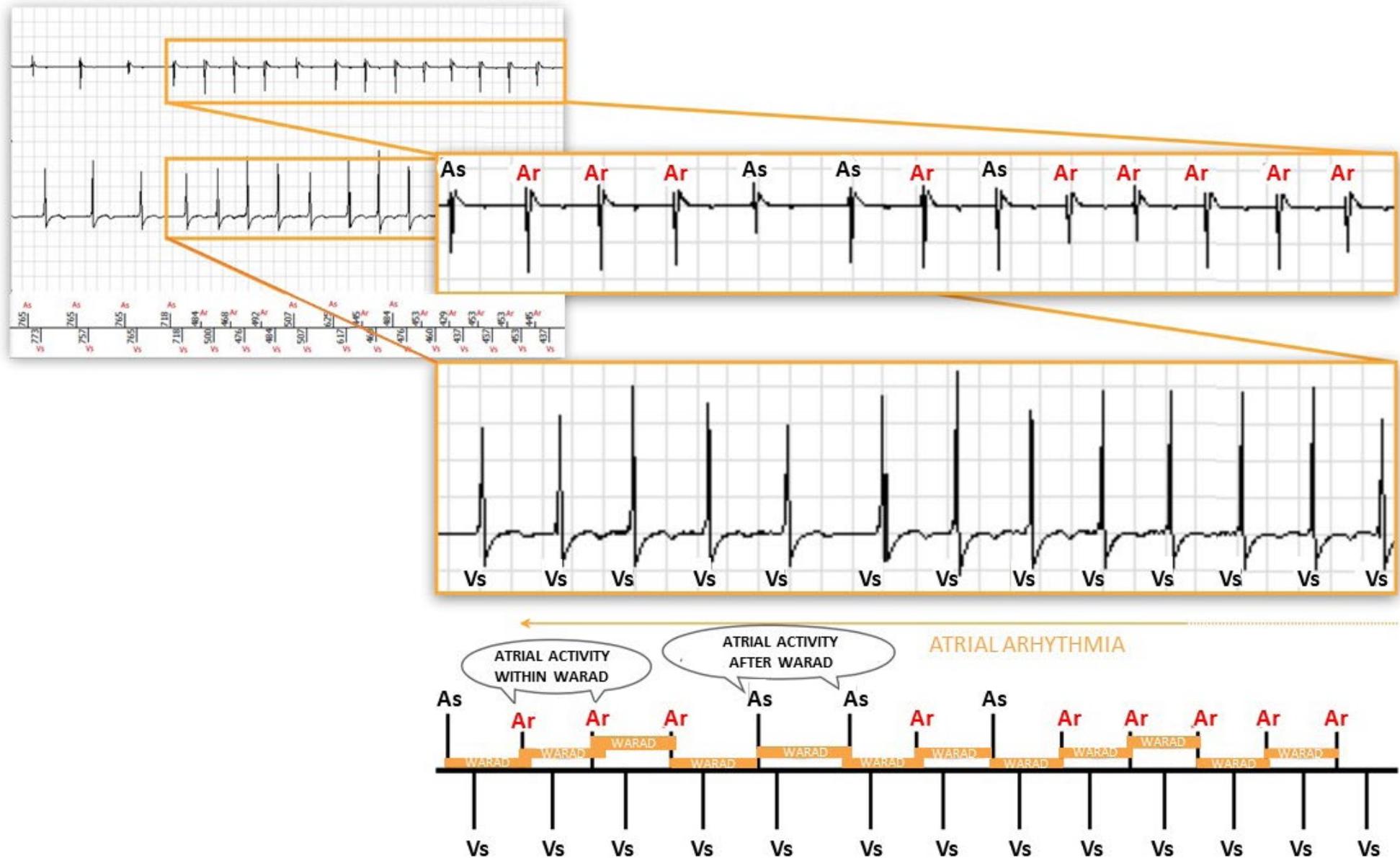
When the SafeR dual-chamber pacing mode is programmed and the pacemaker is operating in ADI mode, a 150 ms refractory period is triggered at the atrial level after atrial pacing. The first 100 ms are an absolute refractory period while the next 50 ms are automatically retriggerable. The value of this period is not programmable.

Following ventricular sensing or pacing, there is an atrial blanking period to avoid crosstalk. On the other hand, as explained above, the great peculiarity of the pacemakers of this manufacturer is that there is no PVARP (refractory period triggered by post-ventricular (sensed or paced) atrial blanking to avoid the occurrence of a pacemaker-mediated tachycardia).

Following atrial sensing or pacing, a relative refractory period is triggered at the atrial level. Its duration is dynamic and is calculated according to atrial rhythm. It is effective only after the end of the atrial refractory period (80 ms, 150 ms or at the end of the AV delay + offset). Its purpose is to detect the acceleration of the atrial rhythm (hence its name: WARAD). When the sinus rhythm is less than 80 min⁻¹, the duration of the WARAD is 62.5% of the previous P-P interval. When the sinus rhythm is greater than (or equal to) 80 min⁻¹, the duration of the WARAD is 75% of the previous P-P interval. At the onset of the fast atrial rhythm, a short AV delay may be triggered on certain sensed P waves during the WARAD if and only if the applied Vs-Vp or Vp-Vp interval is longer than 500 ms. This allows to prevent unnecessarily rapid ventricular pacing at the beginning of an atrial arrhythmia episode before switching to asynchronous mode. During this suspicion phase of atrial rhythm disorder, all sensed atrial events are annotated "Ar" by markers in the refractory periods. The value of the WARAD is then fixed to the value of the WARAD at the time of the very first PAC and cannot exceed 500 ms. The short AV delay that can be triggered after sensing of certain P waves in the WARAD is 30 ms (not programmable). In addition to reduce or eliminate the risk of pacemaker-mediated tachycardia, this short AV delay can reduce the duration of atrial refractory periods in order to better detect fast atrial arrhythmias.

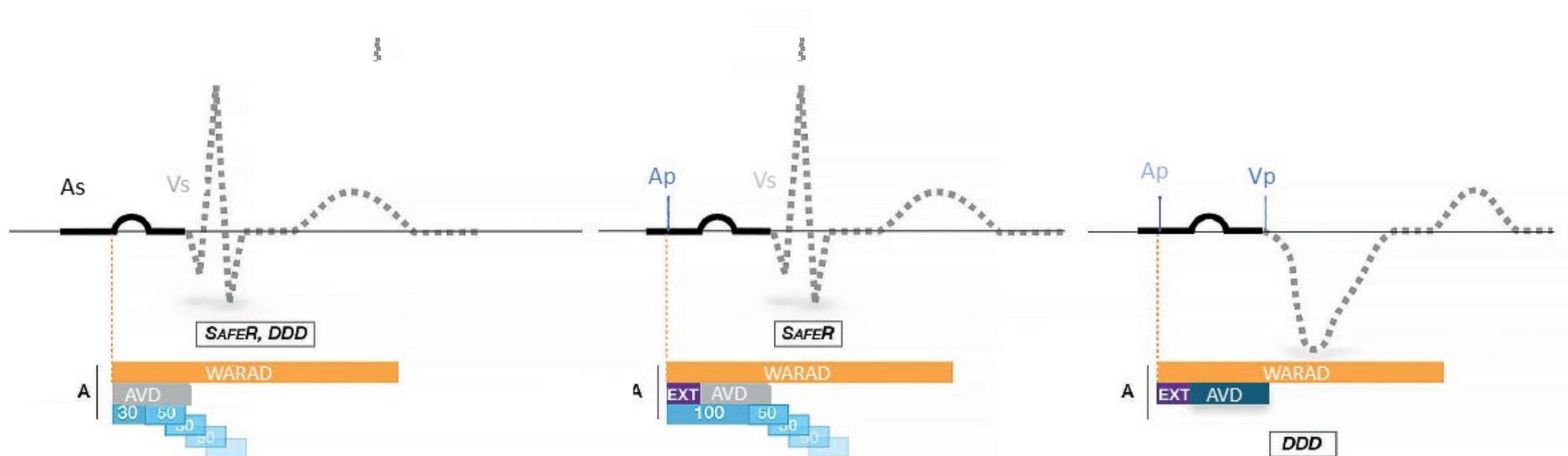
The WARAD is an atrial refractory period specific to MicroPort™ dual-chamber devices (triggered by atrial sensing or pacing) no PVARP (atrial refractory period triggered by ventricular sensing or pacing in MicroPort dual-chamber devices).

Atrioventricular Delay and Refractory Periods



COMMENTS (CONTINUED)

Following a sensed ventricular beat considered as a PVC, an atrial relative refractory period (ARP) is triggered at the atrial level. Its duration is 500 ms and is applied on a maximum of 3 consecutive PVCs. A PVC is defined as ventricular activity not preceded by atrial activity (within an interval of -31 and -300 ms relative to a PVC in DDD mode and a limitless interval in SafeR mode). The sensing of atrial activity in this refractory period is marked as Ar and does not trigger an AV delay. The objective of this refractory period is to reduce the risk of PMT following the occurrence of a PVC.

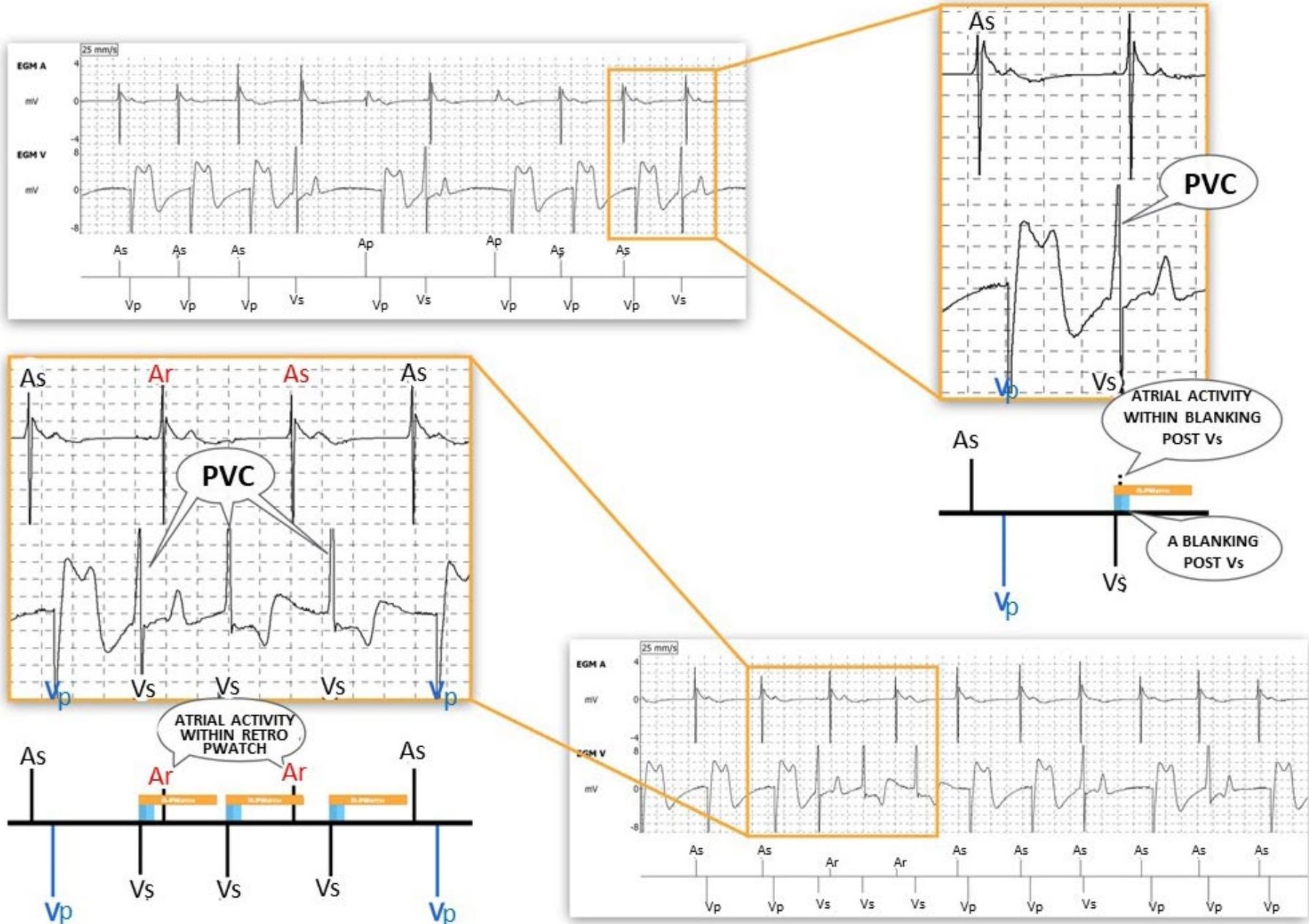


Tracing 39: WARAD + retroPwatch

TRACING 2

On both tracings, initial atrial sensing and ventricular pacing; on the top tracing, premature ventricular contraction followed by atrial activity falling in the post-ventricular atrial blanking (no marker); on the bottom tracing, premature ventricular contraction followed by atrial activity falling in the ARP (Ar marker) and not triggering an AV delay;

Atrioventricular Delay and Refractory Periods



Patient

63-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the pacemaker switches according to AVB I criterion
- B. the pacemaker switches according to AVB II criterion
- C. the pacemaker switches following the occurrence of an AIVR with retrograde conduction
- D. at the end of the tracing, there is an atrial tachycardia
- E. at the end of the tracing, there is a pacemaker-mediated tachycardia

TRACING

At the beginning of the tracing, there is atrial sensing and ventricular sensing (SafeR mode, operating in ADI mode); acceleration of ventricular rhythm, onset of an AIVR (Accelerated Idioventricular Rhythm) with 1:1 retrograde conduction; long pseudo-PR pattern; after 6 consecutive cycles with a PR value greater than the programmed value, switching to DDD mode; on the first paced cycle, long AV delay (300 ms) favoring retrograde conduction and onset of a PMT; after a series of 8 As-Vp cycles (AV delay 250 ms), suspicion of PMT and confirmation phase; prolongation of the AV delay by 50 ms (300 ms) over one cycle, delaying the subsequent ventricular pacing; analysis of the timing of the ensuing atrial cycle is indicative of a PMT; indeed, the As-As interval is prolonged by about 50 ms, demonstrating that it is a retrograde conduction and that the timing of the atrial occurrence depends on the paced ventricle; this As-As interval would have otherwise remained unchanged in the presence of atrial tachycardia, the differential diagnosis in this setting; the device applies a post-ventricular atrial refractory period of 500 ms on the next cycle; the retrograde atrial activity falls in this refractory period, is marked Ar and does not generate an AV delay which terminates the tachycardia and confirms the diagnosis of PMT;

COMMENTS

The onset of a PMT involves the programming of an atrial tracking mode (DDD or VDD), the permeability of retrograde conduction, and a momentary loss of atrioventricular synchrony. In this patient, the occurrence of an IRVA with retrograde conduction favors the occurrence of a switch to DDD mode and the onset of a PMT.

The PMT results from the sensing of a retrograde P' wave outside of the refractory periods which often triggers prolonged AV delay, which again promotes retrograde conduction after ventricular pacing. A PMT is therefore a repetitive sequence in which the pacemaker responds to each retrograde P' wave by pacing the ventricle at a high rate which then generates a retrograde P' wave.

For pacemakers from other manufacturers, the prevention of PMT occurrence is based on the programming of a PVARP longer than the retrograde conduction time. At Microport™, this protection is based on the WARAD which maintains a long atrial refractory period. In addition, following the sensing of a PVC, the atrial refractory period is 500 ms (ARP). This ARP applies to a maximum of 3 successive PVCs. The P waves sensed in the ARP corresponds to Ar marker.

The «Anti-PMT» algorithm is always active in atrial tracking mode (in older platforms before Alizea range). The functioning of this PMT detection and termination algorithm

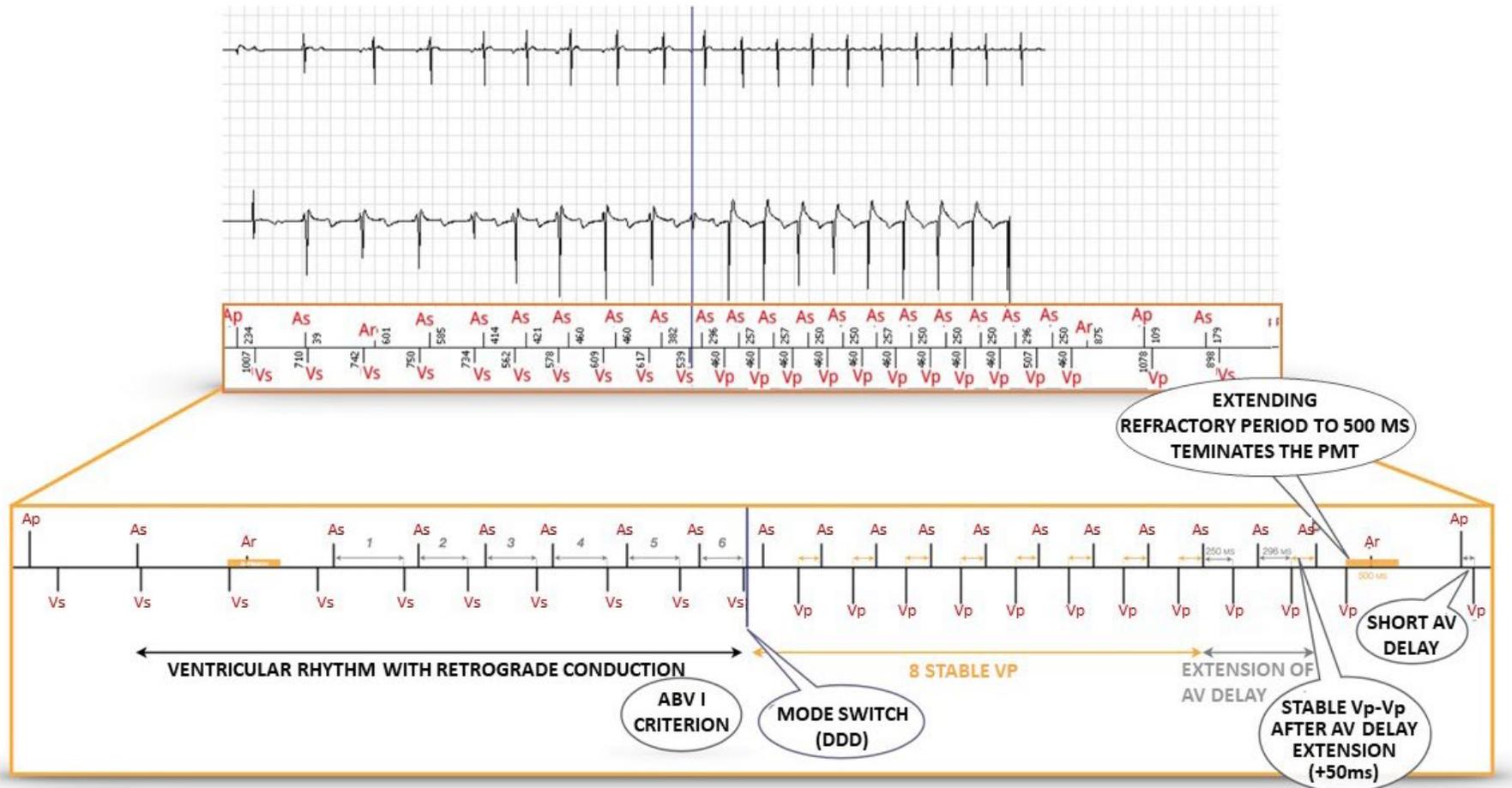
can be broken down into 3 phases:

- initial detection phase over 8 consecutive Vp-As cycles (atrial sensing ventricular pacing outside of the WARAD); the device measures the retrograde conduction time (VP) and suspects a PMT if the VP intervals are stable (within 30 ms) and short (< 470 ms);
- confirmation phase over 2 cycles; the device modulates the AV delay (prolonging or decreasing by 50 ms per the programmed maximum rate) to verify the stability of the VP interval; if stable, the device concludes to a PMT and attempts to terminate; if not, sinus tachycardia or atrial tachycardia and PV synchronization is continued.
- termination phase; a relative atrial refractory period of 500 ms after ventricular pacing is applied for one cycle such so that the next atrial event is sensed in this refractory period (Ar-marker); this atrial activity is not synchronized to the ventricle for 1 cycle (no AV delay is triggered); if it is indeed a PMT, the tachycardia is terminated.

In the AIDA/PM tab, the number of PMT episodes is provided in the statistical data. The counter is saturated after reaching 255 episodes. On the other hand, it is not

The PMT detection and termination algorithm cannot be switched off in pacemaker platforms previous to ALizea range. If the anti-PMT option is set to « TERMIN », the device diagnoses and terminates the PMT. If the anti-PMT option is programmed to « REPROG » the device diagnoses and terminates the PMT. In addition, it automatically shortens the rest and exercise AV delays by 15 ms (limit of 125 ms for the rest AV delay and 80 ms for the exercise AV delay) if more than 10 PMT per day are detected in order to reduce the risk of occurrence of a new PMT (favored by long AV delays).

Atrioventricular Delay and Refractory Periods



COMMENTS (CONTINUED)

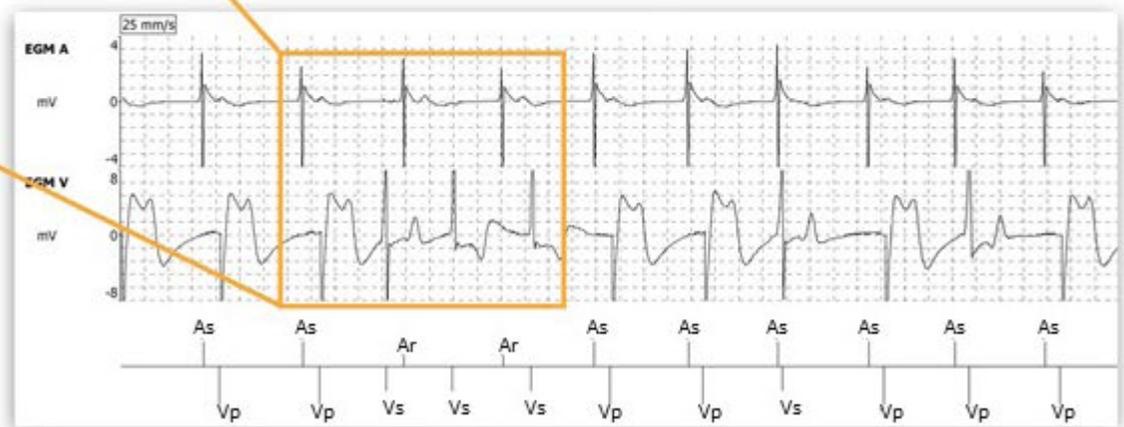
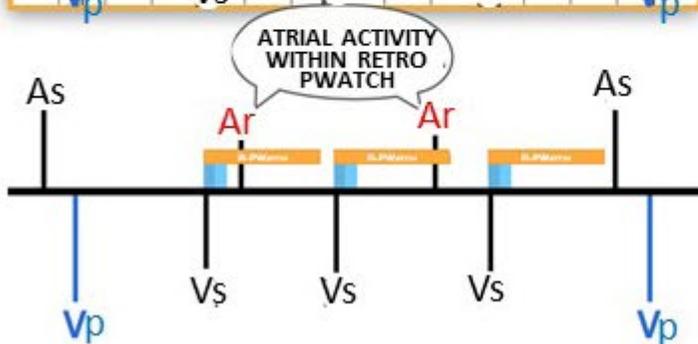
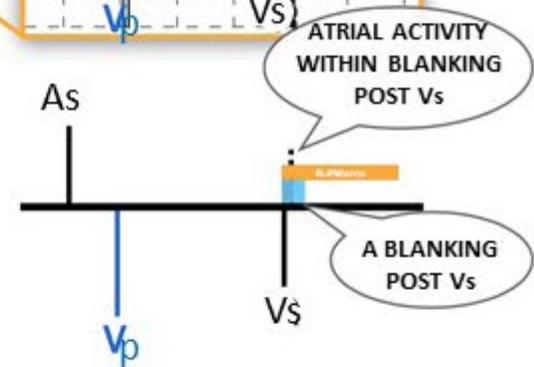
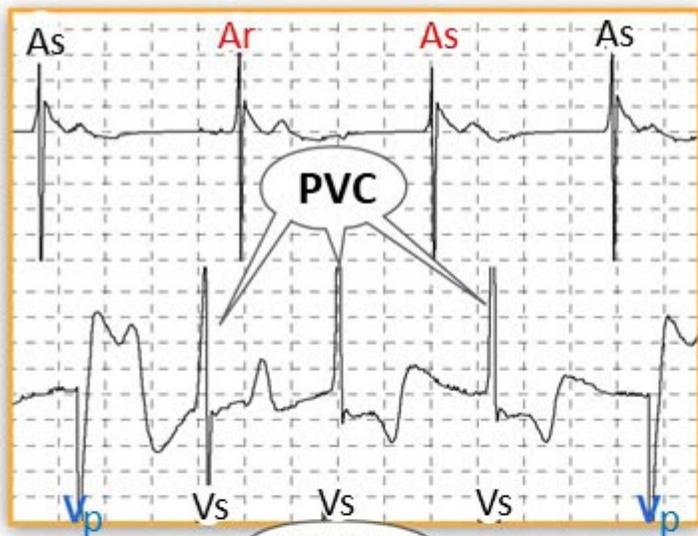
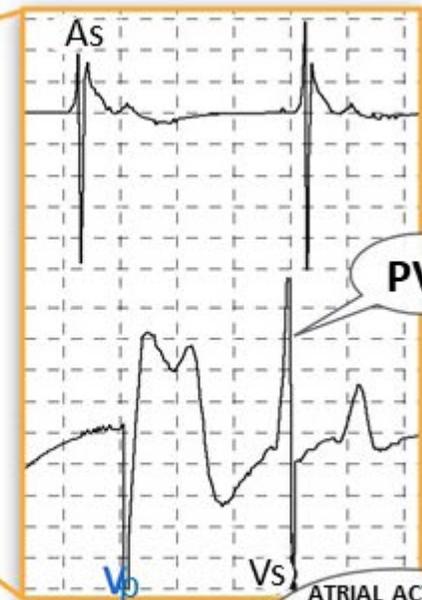
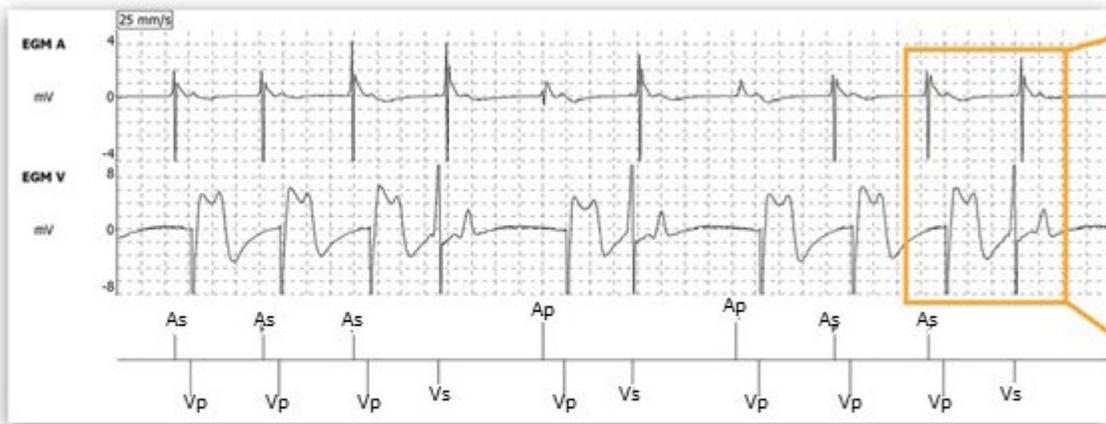
possible to visualize the EGMs corresponding to the PMT episodes diagnosed by the device

Parameters screen of the previous PM generations. Two available choices: Termin. and Reprog.

Basic Parameters		Pacing/Sensing		Advanced parameters	
Mode	SafeR-R (AAIR<=>DDDR)	A sensitivity	0.4 mV Bipolar	Prevention of A arrhythmia	>>
Basic Rate	60 min-1	Atrial Pacing	3.5 V 0.35 ms Unipolar	Rate Response Parameters	>>
Rest Rate	60 min-1	V sensitivity	2.5 mV Bipolar	SafeR : AAIR=>DDD criteria	>>
Max Rate	130 min-1	V Pacing	3.5 V 0.35 ms Unipolar	Refractory period	>>
Hysteresis	0 %			Implantation Auto Detection	>>
AVD Rest/Exerc.	155 ms 80 ms	Basic Functions			
AVD Paced/Sensed Offset	65 ms	Smoothing	Off		
		Mode Switch	On		
		Anti-PMT	Reprog	Termin.	
		Special Functions		Reprog	
		Auto-sensing A / V	Monitor Monitor		
		V AutoThresh	Off		
		Preprogrammed Settings			

Pacing/Sensing	Brady	Remote	Anti-Brugada Detect
MRI			
MRI Mode	Off		
Basic Functions			
Smoothing	Off		
Mode Switch/Fallback rate	On 60 min-1		
Anti-PMT	Reprog	Off	Termin. Reprog
Rate Response			
Rate response	Learn		
Sensor	Twin Trace		
SafeR : AAIR=>DDD criteria			
AVB I switch	Rest/Exer		
Long PR at rest	350 ms		
Long PR at exercise	250 ms		
Max pause	3 s		
Apnea			
Monitoring	On		
Night period	00:00-05:00		
Refractory period			
Post V Atrial Blanking	150 ms		
Post R Atrial Blanking	95 ms		
MV Configuration			
MV Configuration	A Bipolar		
Prevention of A arrhythmia			
Overdrive	Off		
PAC pause suppression	Off		
PAC acceleration	Off		
Preprogrammed Settings			
Erase		Save	
Name			

Brady parameters screen of the ALIZEA, BOREA, CELEA PM ranges. Three available choices: Off, Termin. and Reprog.



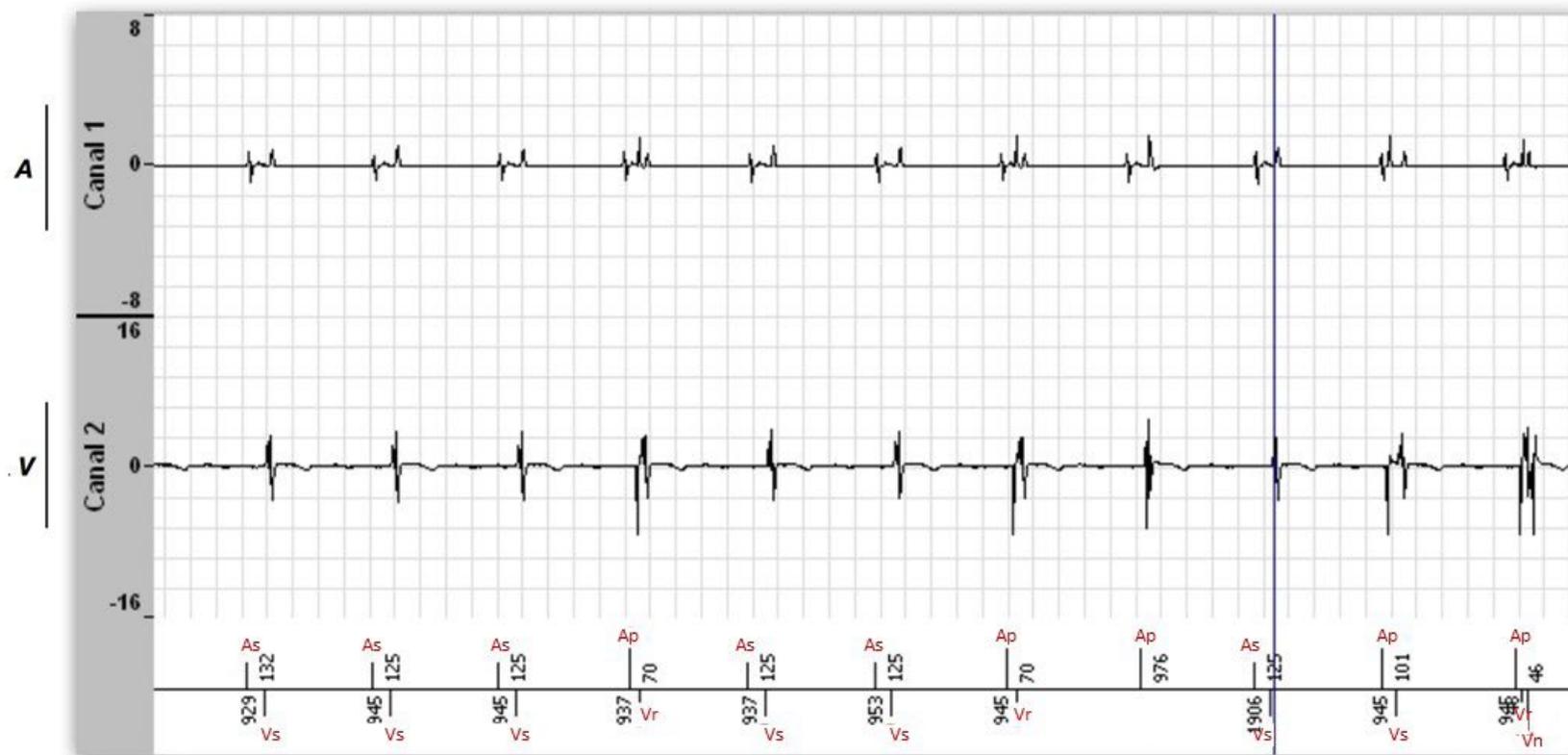
Patient

63-year-old man; implantation of a MicroPort™ Reply DR dual-chamber pacemaker for sinus dysfunction; SafeR mode programming; recording of DDD mode-switches in the device memory;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the pacemaker switches according to AVB II criterion
- B. the pacemaker switches according to AVB III criterion
- C. in SafeR mode, there is no post-atrial ventricular blanking
- D. in SafeR mode, atrial pacing followed by ventricular sensing in the safety window is considered as blocked atrial activity
- E. in DDD mode, atrial pacing followed by ventricular sensing in the safety window is followed by forced ventricular pacing after an AV delay of 95 ms



TRACING

Initial atrial sensing and ventricular sensing (As-Vs cycles); atrial undersensing and atrial pacing with QRS complex sensed in the safety window (r); this cycle is considered as a blocked paced atrial beat; atrial undersensing on 2 consecutive cycles with atrial pacing; on the first cycle, the QRS complex falls in the safety window (Vr), on the second cycle it falls in the post-atrial ventricular blanking; these 2 consecutive atrial paced beats are considered as blocked; AVB III criterion and switching to DDD mode (vertical line); still atrial undersensing with 2 atrial paced beats; on the first cycle, the QRS is sensed after the safety window and is marked Vs; on the second cycle, the QRS complex is sensed in the safety window causing forced ventricular pacing after a 95ms AV delay (cycle Ap-Vr-Vn);

COMMENTS

This tracing allows to highlight the specificities of the post-atrial ventricular refractory periods. In SafeR mode, even if the functioning of the device is designed to be AAI or ADI mode, it is very important to protect the ventricular channel after atrial pacing to avoid crosstalk which could lead to the occurrence of an asystole during an AV block episode. Indeed, atrial pacing is delivered in Volts while ventricular sensing functions in mV with a ratio of 1 per 1000; the atrial stimulus will be sensed by the ventricular channel in the absence of protection, hence the need for a refractory period.

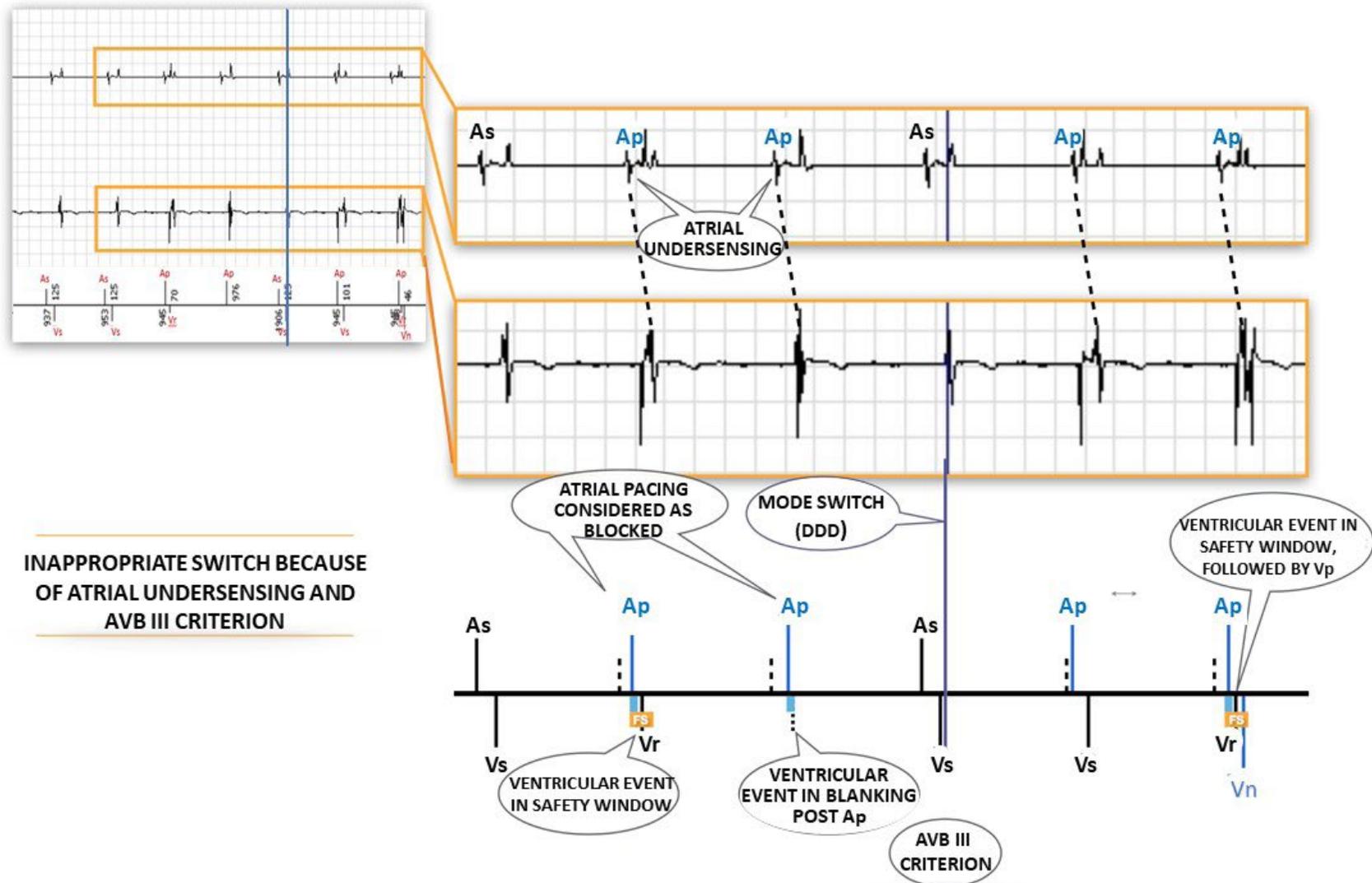
When the pacemaker operates in SafeR mode or DDD mode, atrial pacing triggers a ventricular blanking followed by a safety window. However, the consequences of sensing in the safety window differ according to whether the pacemaker is operating in SafeR DDD or ADI mode.

Post-atrial ventricular blanking is designed to prevent sensing of the atrial stimulus by the ventricular sensing channel which would result in ventricular inhibition. In a MicroPort™ pacemaker, following atrial pacing, a 30 ms refractory period is triggered at the ventricular level. The first 15 ms are an absolute refractory period while the next 15 ms are automatically retriggerable the event of ventricular sensing. The value of this period is not programmable.

The safety window is a ventricular sensing period which complements post-atrial ventricular blanking. As the post-atrial ventricular blanking, is initiated after atrial pacing and is designed to prevent ventricular asystole due to inappropriate inhibition of ventricular pacing by sensing of the stimulus (or of atrial depolarization).

The consequences of ventricular sensing differ according to the mode (SafeR DDD or ADI):

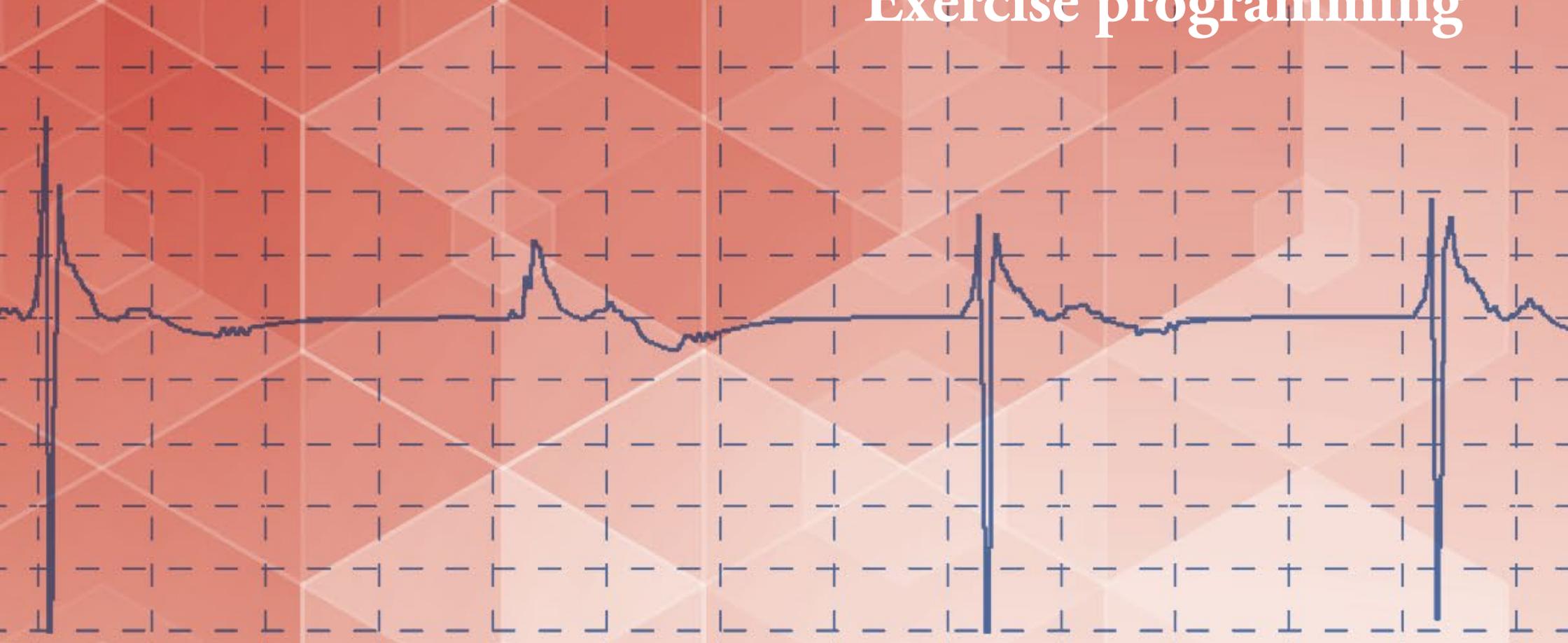
- in DDD mode: ventricular sensing after atrial pacing is considered non-physiological and causes ventricular pacing at the end of the safety window. The short AV delay pattern allows to recognize pacing in a safety window on the electrocardiogram. If the event sensed in the safety window is the result of crosstalk or oversensed noise, the pacing pulse provides effective ventricular capture at the end of the safety window. If the event sensed in the safety window corresponds to a late premature ventricular contraction or atrioventricular conduction, the pacing at the end of the safety window occurs early enough in the absolute myocardial ventricular refractory period to avoid pacing at the apex of the T wave. In MicroPort™ pacemakers, following atrial pacing, a 95 ms relative refractory period is triggered at the ventricular level. The value of this period is not programmable. It is only effective after the end of the post-atrial ventricular blanking. If ventricular sensing occurs between the end of the post-atrial ventricular blanking and the end of the safety window, then ventricular pacing is delivered at the end of the safety window.
- in SafeR mode: when the SafeR dual-chamber pacing mode is programmed and the pacemaker is operating in AAI mode (more precisely in ADI), there is also a safety window that follows the post-atrial ventricular blanking. Ventricular sensing in the safety window is 1) marked Vr, 2) does not cause pacing at the end of the safety window, 3) is considered as a blocked paced atrial event (Ar cycle). Switching to DDD mode avoids prolonged asystole if the sensing corresponds to crosstalk. On the other hand, switching may be inappropriate in the case of late premature ventricular contractions for example (switching in the absence of conduction disorder).



The analysis of marker chains and EGM of a pacemaker operating in SafeR mode allows to see the EGMs corresponding to the switch related to ventricular sensing in the safety window. Often, these are late premature ventricular contractions or an atrial sensing failure as in the present example.



Exercise programming



Patient

63-year-old man implanted with a MicroPort™ dual-chamber pacemaker for complete atrioventricular block; maximum synchronous rate at 140 bpm, atrial sensing: Autosensing; sensation of block/pnea during exertion; recording of a tracing corresponding to the symptoms described by the patient;

Quiz

Regarding this EGM, what is(are) the correct answer(s)?

- A. the drop in ventricular rate is related to Wenckebach phenomenon
- B. the drop in ventricular rate is related to 2:1 phenomenon (1 in 2 atrial activities occurring in the PVARP)
- C. the drop in ventricular rate is related to ventricular capture failure
- D. the drop in ventricular rate is initially related to atrial undersensing
- E. the drop in ventricular rate is related to suspicion of atrial arrhythmia by the device

TRACING

At the beginning of the tracing, heart rate is faster than 120 bpm (relatively large effort) with synchrony between atrial and ventricular pacing; variability of the amplitude of the atrial signals; undersensing of sinus activity and decrease in ventricular pacing rate; atrial sensing and ventricular escape (pacemaker-dependent patient); new atrial undersensing; atrial activity sensed but with "Ar" marker since falling in the WARAD; the duration of the WARAD is dependent on the duration of the preceding AA interval (at this rate, 75% of the AA interval); the device identifies a prolonged AA interval due to atrial undersensing; absence of ventricular pacing as this would result in pacing faster than 120 bpm which is not possible for a P-wave (Ar) occurring in the WARAD; atrial sensing in the WARAD and ventricular pacing with a characteristic short AV delay of 30 ms; continued P-wave (Ar) sensing in the WARAD with synchrony of one in two atrial activities due to short AV delay;

COMMENTS

The symptoms experienced by the patient were related to a sudden and prolonged decrease in heart rate secondary to atrial undersensing. Exertion and increased breathing movements are often associated with impaired atrial sensing. It is therefore necessary to ensure a sufficient margin when programming the atrial sensitivity.

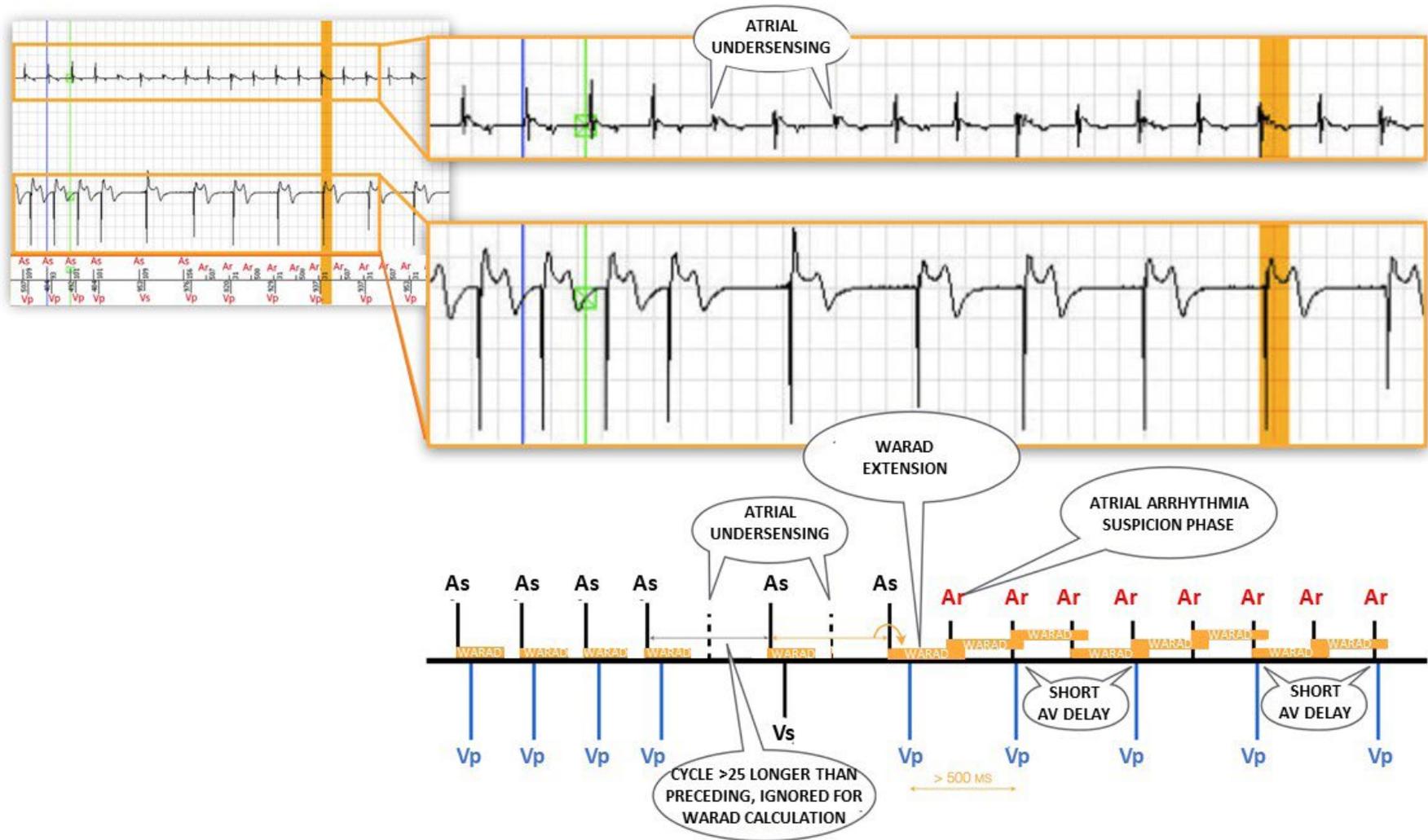
This tracing illustrates two important elements in the operation of MicroPort™ pacemakers: 1) atrial Autosensing: the amplitude of the signals is averaged over 8 consecutive cycles and the sensitivity is programmed at 37.5% of this mean value. In this patient, the quality of the atrial sensing was entirely suitable (> 5 mV) at rest. During exercise, one can observe that the amplitude of the atrial signals displayed significant variations with the respiratory cycles. When the sensed atrial signals are of high amplitude and atrial Autosensing is programmed, the atrial sensitivity level adjusts to the relatively high values (pacemaker is poorly sensitive) explaining the possible undersensing if the ensuing atrial signals are of low voltage. On this tracing, some P waves are undersensed at the beginning of the tracing, with the sensitivity value progressively adjusting thereafter (average over 8 cycles) with sensing of all the P waves. The initial fall in rate is therefore in relation to atrial undersensing. 2) the WARAD and the fallback algorithm: the atrial undersensing induces a false diagnosis of an atrial bradycardia (undersensing) followed by an acceleration (proper sensing). When proper atrial sensing resumes a P wave is sensed in the WARAD (calculated on the second long cycle and applied on the next cycle; the duration of the first long cycle is greater than 25% of the preceding cycle and by definition is not taken into

account for the update of the WARAD). The WARAD value is then fixed on the value of this first activity deemed premature. All of the following P waves are therefore sensed in the WARAD which lead to functioning in 2:1 mode (one in 2 blocked atrial activities) followed by a fallback in asynchronous mode despite a return to perfect atrial sensing. There is a rule that limits the ventricular pacing rate when one or more atrial activities are sensed in the WARAD. During suspicion of atrial arrhythmia, the ventricular pacing cannot exceed 120 bpm.

Throughout the duration of the suspected onset of atrial arrhythmia, the applied AV delays are 31 ms in order to shorten the maximum duration of the atrial refractory periods and to allow the diagnosis of a fast atrial arrhythmia (very high 2:1 point). Another condition to fallback mode is the atrial rate: it must be > 120 bpm.

In this patient, a change in atrial sensitivity (Autosensing function switched off and fixed atrial sensitivity) enabled solving the problem and eliminating the symptoms.

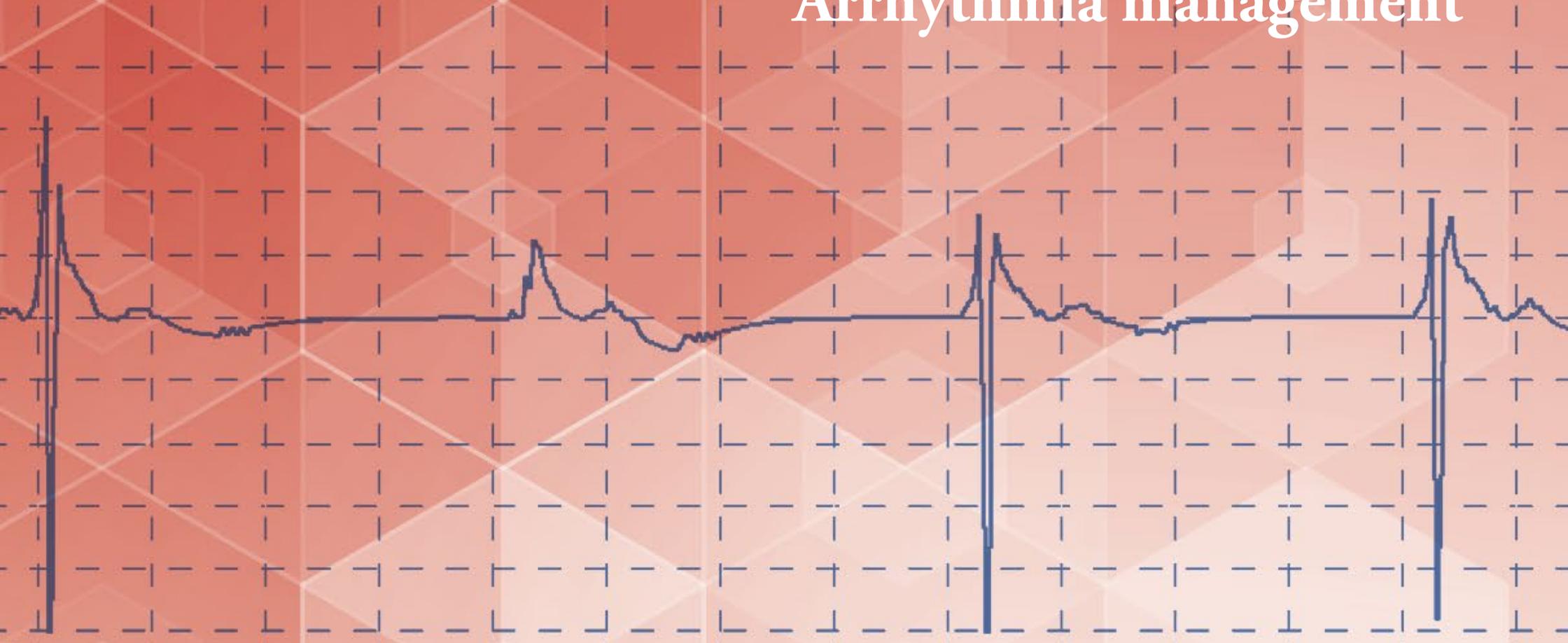
Different hypotheses must be evoked upon occurrence of symptoms during exertion in a patient implanted with a MicroPort™ pacemaker.
Intermittent or prolonged atrial undersensing may cause a sudden drop in rate.





Stimulateur Cardiaque Implantable - **Chapter 7**

Arrhythmia management



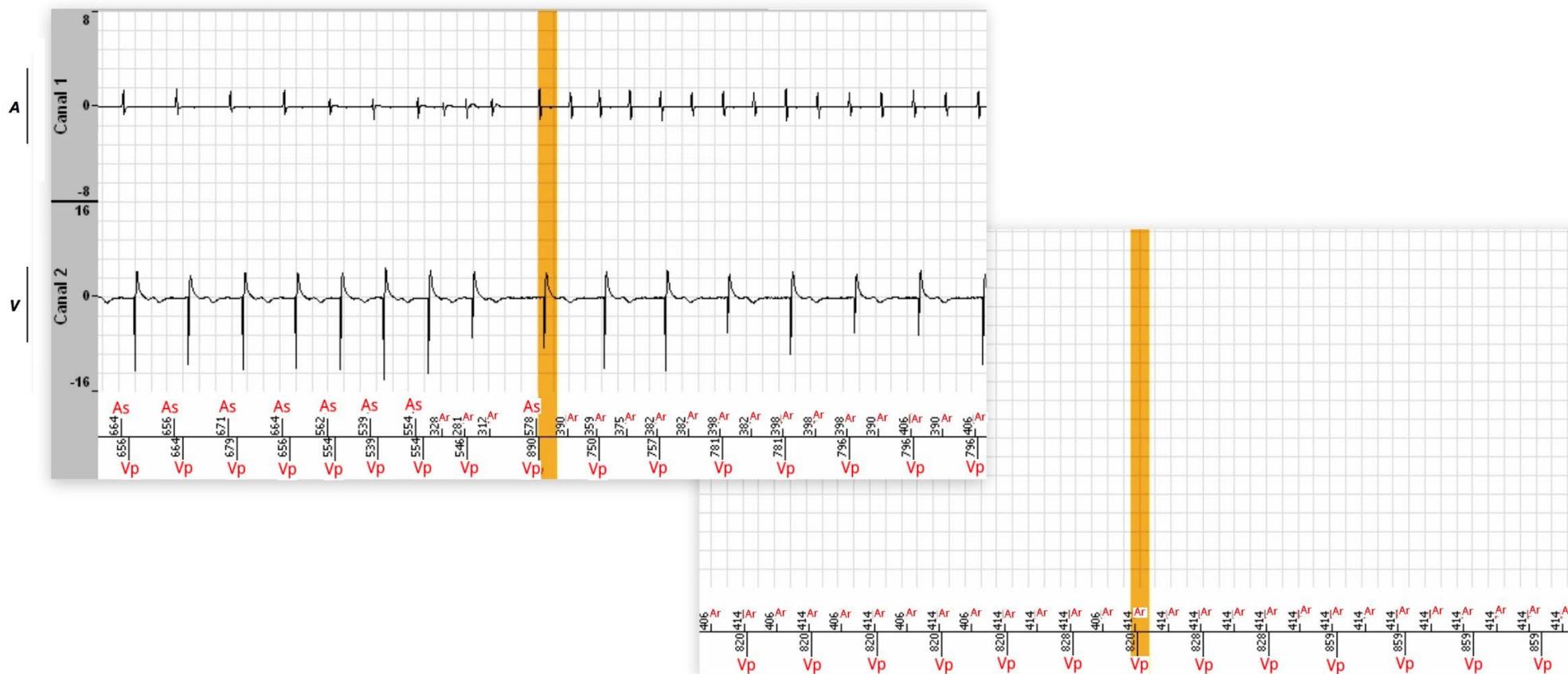
Patient

Patient with complete atrioventricular block implanted with a dual-chamber pacemaker;

Quiz

What is(are) the correct answer(s) for a MicroPort™ pacemaker?

- A. the mode switch algorithm is based on the sensing of 8 consecutive fast atrial cycles
- B. the mode switch algorithm is based on the measurement of the median of 12 consecutive atrial cycles
- C. the minimum duration of an atrial arrhythmia to trigger mode switch is programmable
- D. the minimum duration of an atrial arrhythmia to trigger mode switch is not programmable
- E. the mode switch algorithm is based the measurement of a filtered atrial rate



TRACING

At the beginning of the tracing, the rhythm is sinus at a relatively fast rate (90 beats/minute) followed by ventricular pacing; there is a subsequent episode of atrial arrhythmia, the atrial cycles being correctly sensed in the WARAD; this arrhythmia subsequently stabilizes at a rate of approximately 150 beats/minute; during the suspicion phase of atrial arrhythmia, the tracing demonstrates ventricular pacing with a short AV delay of 30 ms, with only one out of two atrial activities being synchronized; it is indeed not possible to pace the ventricle during this suspicion phase at a rate higher than 120 beats/minute (not possible to after each wave in the WARAD which would have led to ventricular pacing at 150 beats/minute); the device then switched to the asynchronous mode when the primary criterion was fulfilled;

COMMENTS

The management of pacemaker-implanted patients with atrial arrhythmia episodes is complex given the different types of mechanisms known to trigger atrial arrhythmias and the risk of runaway ventricular pacing due to the sensing of a fast atrial rhythm. The mode switch algorithm which is activated by default allows the pacemaker to automatically switch from an atrial tracking mode (DDD or VDD) to an asynchronous mode without atrial tracking (DDI) during an atrial arrhythmia episode. When the atrial tachyarrhythmia is terminated, the switch mode reverts to the programmed synchronous pacing mode. The proper operation of a fallback algorithm involves: 1) rapid triggering to avoid prolonged rapid ventricular pacing during the initial arrhythmia detection phase, 2) ability to rapidly revert back to a synchronous mode at the end of the arrhythmia episode, 3) good ability to diagnose the atrial arrhythmia even in the presence of atrial signals of varying amplitude and rate, 4) ability to avoid mode switch in response to A-V crosstalk or atrial noise.

For a Microport™ pacemaker, the fallback can be divided into several distinct phases: a suspicion/confirmation phase, a dissociation phase and a reassociation phase.

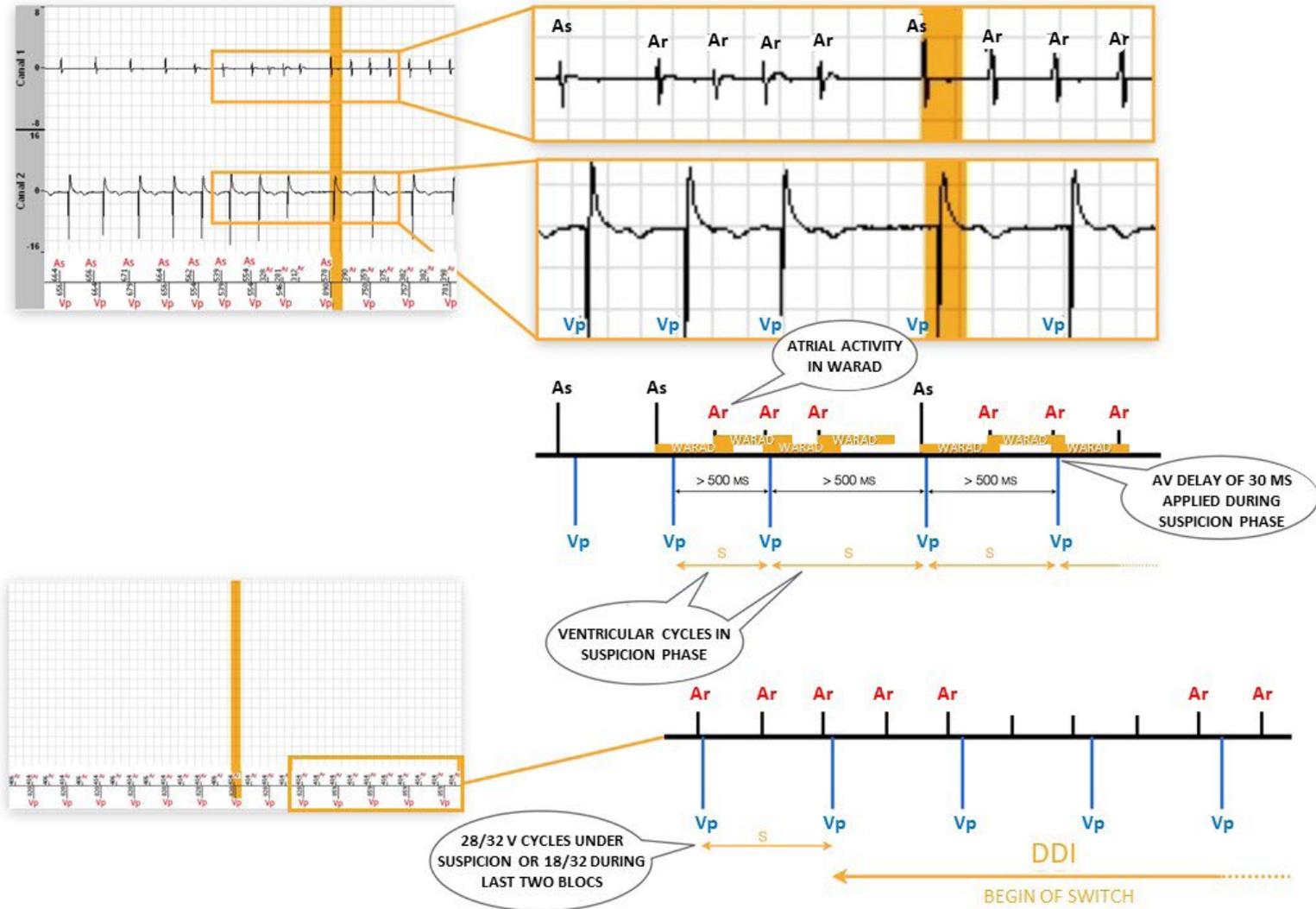
suspicion/confirmation phase of an atrial arrhythmia: the suspicion of an atrial arrhythmia occurs when multiple atrial cycles are sensed in the WARAD. The value of the WARAD is then fixed to the WARAD calculated at the time of the very first PAC and cannot exceed 500 ms. At the onset of the rapid atrial rate, a short AV delay may be triggered on some P waves sensed in the WARAD if and only if the resulting Vs-Vp or Vp-Vp is longer than 500 ms. This prevents from very fast ventricular pacing at the beginning of the episode prior to switch to asynchronous mode. The short AV delay triggered after sensing of certain P waves in the WARAD is 30 ms (not programmable) yielding a

characteristic electrocardiographic pattern. Ventricular cycles with at least one sensed atrial event in a WARAD are considered « suspicious ». As soon as a ventricular cycle with suspicion of atrial arrhythmia is sensed, the mode switch algorithm begins an analysis on the next 32 ventricular cycles (analysis by blocks of 32 ventricular cycles may be necessary). Atrial arrhythmia is confirmed if one of the two following criteria is met: 1) 28 or more ventricular cycles in suspicion over the previous 32 ventricular cycles (primary criterion); 2) 18 or more ventricular cycles in suspicion over the previous two blocks of 32 ventricular cycles (secondary criterion). The primary criterion is usually met in about 15 seconds. The secondary criterion may allow mode switch despite intermittent atrial undersensing.

dissociation phase: once one of the 2 mode switch criteria is reached, the pacemaker switches to an asynchronous mode (DDI). The ventricular pacing rate gradually decreases (the ventricular escape interval increases by 30 ms every 12 cycles) towards the basic rate, the rate responsive sensor rate, or the rest rate.

reassociation phase: upon termination of the atrial arrhythmia, the pacemaker switches back to the programmed synchronous mode. A-V reassociation only takes place when both the atrial rate and ventricular rate fall below 110 beats/minute. A 500 ms ARP (atrial refractory period) is applied to the first reassociated ventricular event to avoid triggering a PMT. The pacing rate of the DDI mode is gradually increased step by step (65 ms every 12 cycles) until matching the atrial rate. As soon as 12 consecutive cycles are paced at the atrial and ventricular sites the pacing mode changes from DDI to DDD.

The mode switch algorithm is based on the sensing of atrial intervals in the WARAD and on the sensing of ventricular intervals considered as suspicious. The suspicion phase can be relatively prolonged (at least 28 ventricular cycles) and associated with ventricular pacing low 120 beats/minute.



COMMENTS (CONTINUED)

Other specific algorithms to prevent the onset of atrial arrhythmias:

- Sinus rhythm overdrive

The goal is to provide permanent atrial pacing slightly above the sinus rhythm to prevent the onset of AF by reducing the atrial pacing interval (-50 ms) following the sensing of (normal, sinus, non-accelerated) P waves (sensing in the INappropriate OVerdriving (INOV) window (and outside the WARAD)). This function is limited by a maximum programmable overdrive rate. This algorithm is inactive by default.

To avoid inappropriate acceleration on late premature atrial contractions, there is a specific window (the INOV window, INappropriate OVerdriving). The value of this late PAC monitoring window is based on the AR or PR conduction time and the maximum overdrive rate. If P wave sensing occurs in the INOV window, the sinus rhythm overdrive function is inhibited.

After 16 « overdrive » cycles, the pacing rate decreases with the programmed rate smoothing (by default very slow). The maximum overdrive rate is programmed in this instance to 100 min⁻¹.

- Post extrasystolic pause suppression

The objective of this algorithm is to prevent the occurrence of atrial fibrillation on a successive short atrial cycle (extrasystole) followed by a long cycle (compensatory pause) sequence.

On a «late» isolated PAC (with a coupling greater than 50% of the last P-P interval), the algorithm triggers an automatic AV delay and a smoothed intermediate escape interval.

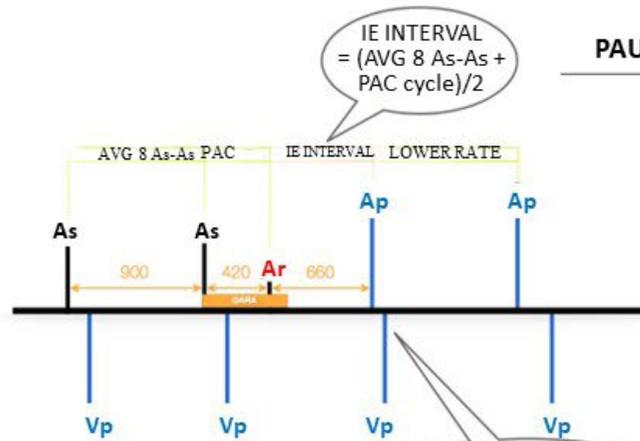
- Acceleration on PAC

To reduce the number of extrasystoles, this algorithm allows a temporary (24 cycles) rate acceleration (~ 5 min⁻¹) following frequent isolated premature atrial complexes (separated by up to 15 normal atrial cycles). By default, this algorithm is inactive. The acceleration phase is halted if the maximum acceleration rate is reached or if the maximum PAC counter is reached. These two stoppage criteria are not programmable. Stoppage is followed by a « definitive » smoothing up to the basic rate.

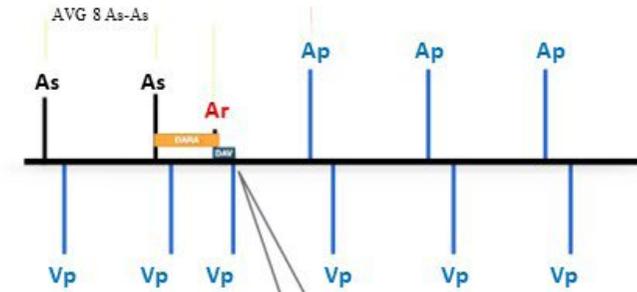
The maximum acceleration rate is calculated as follows: if the atrial rate is less than 90 min⁻¹, the escape interval is 75% of the average of the last eight P-P intervals immediately preceding the first PAC. If not, the escape interval is 75% of the average of the last eight P-P intervals immediately preceding the first PAC + 50 ms.

Basic Parameters	Pacing / Sensing	Advanced parameters
Mode: SafeR (AAI<=>DDD)	A Sensitivity: 0.2 mV Bipolar	MRI Parameters >>
Basic Rate: 60 min ⁻¹	A Pacing: 2.0 V 0.35 ms Unipolar	Prevention of A arrhythmia >>
Rest Rate: 60 min ⁻¹	V Sensitivity: 2.5 mV Bipolar	Rate Response Parameters >>
Max Rate: 130 min ⁻¹	V Pacing: 2.5 V 0.35 ms Unipolar	SafeR : AAI=>DDD criteria >>
Hysteresis: 0%		Refractory period >>
AVD Rest/Exerc.: 250 ms 80 ms		Implantation Auto Detection >>
AVD Paced/Sensed Offset: 65 ms		Lead Polarity Switch >>
	Basic Functions	

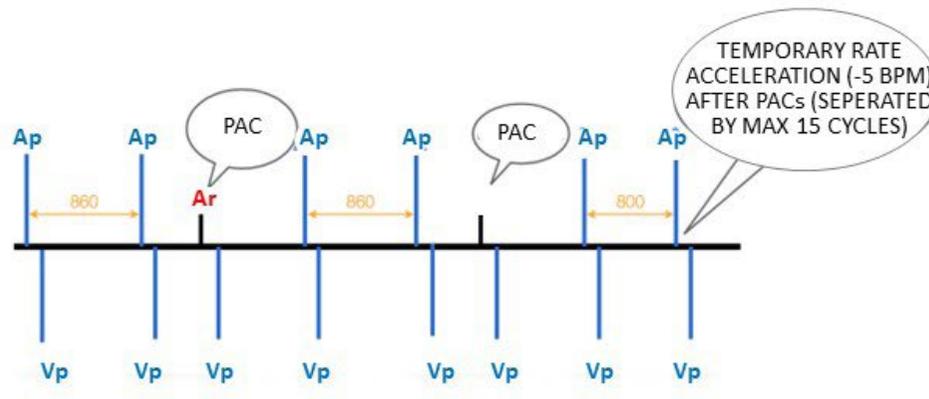
PAUSE SUPPRESSION AFTER PAC



MAINTAINING A STABLE RHYTHM TO AVOID LONG-SHORT-LONG CYCLE

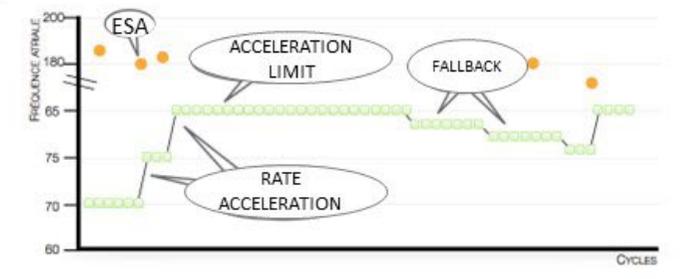


« LATE » PAC (>50% last As-As) TRIGGERS AVD AND IE INTERVAL



RATE ACCELERATION BY PACS

TEMPORARY RATE ACCELERATION (-5 BPM) AFTER PACs (SEPERATED BY MAX 15 CYCLES)



SCHEMATIC OVERVIEW OF THE PAC ACCELERATION ALGORITHM

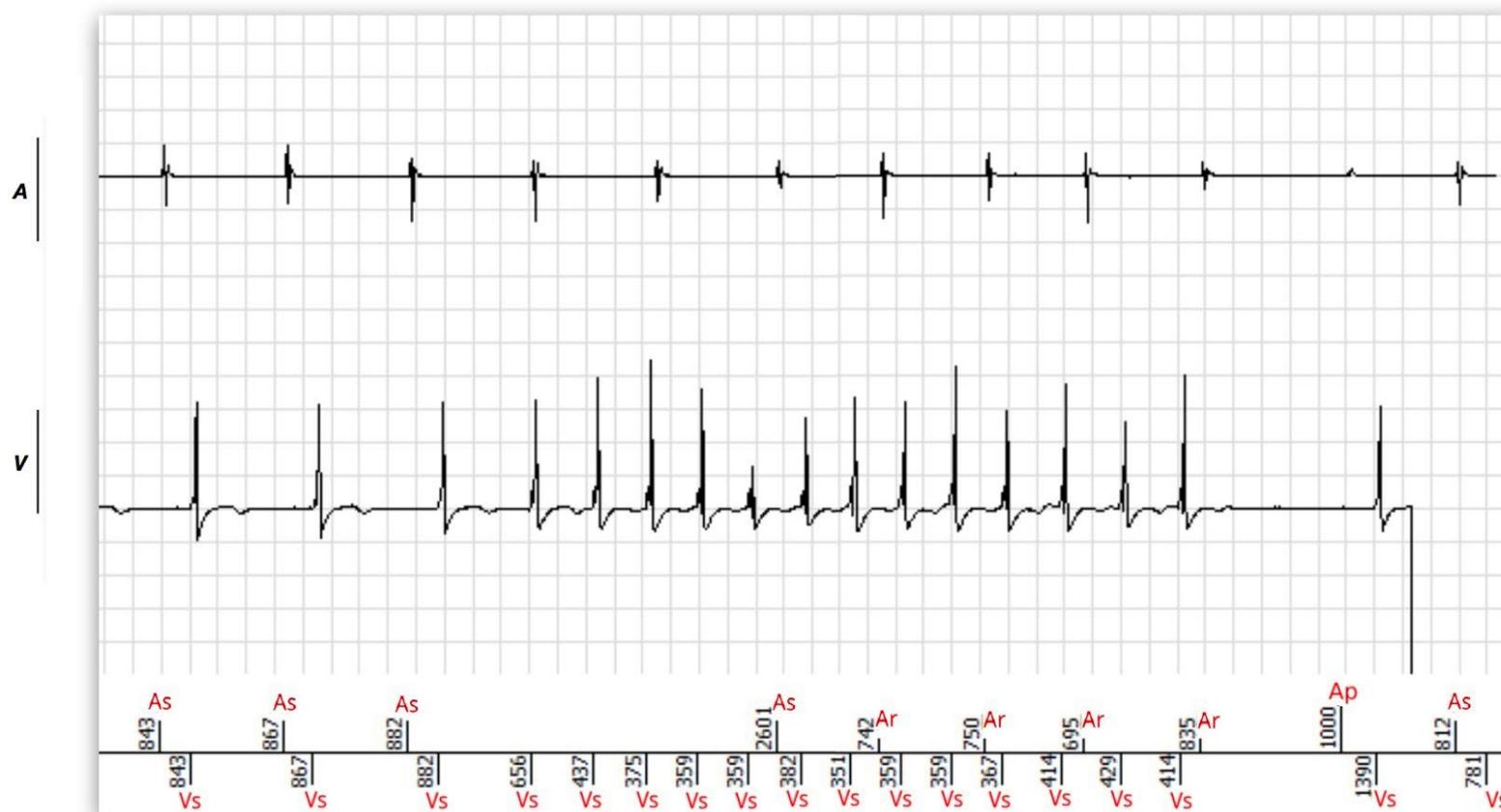
Patient

Patient implanted with a dual-chamber pacemaker for sinus dysfunction; recording of an episode of non-sustained ventricular tachycardia;

Quiz

What is (are) the correct answer(s) for this tracing?

- A. this is a non-sustained VT episode
- B. this is a non-sustained atrial tachycardia episode
- C. this is a junctional tachycardia episode
- D. there is atrial sensing failure
- E. atrial activities fall in the post-ventricular atrial blanking



TRACING

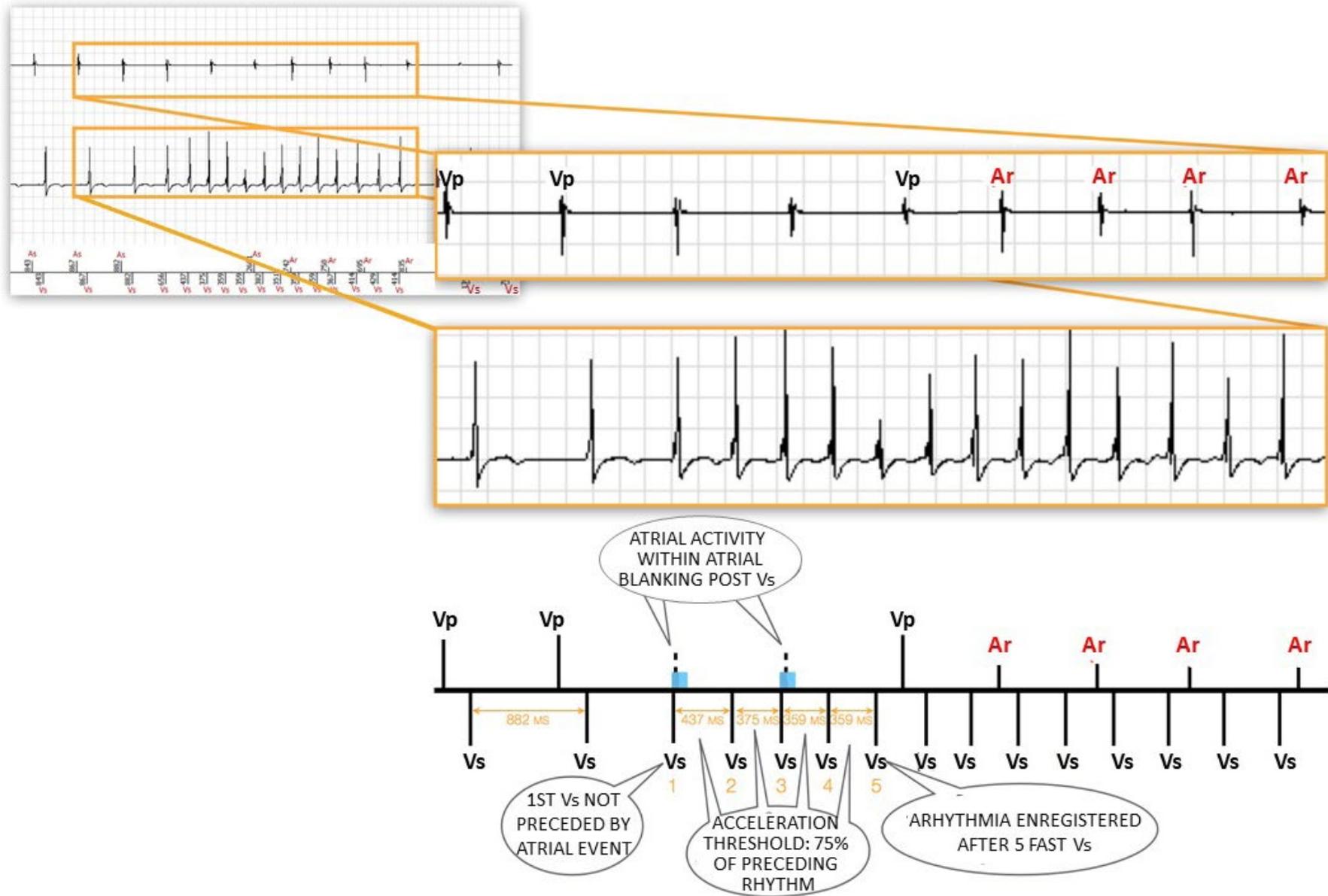
Non-sustained ventricular tachycardia with atrioventricular dissociation; spontaneous termination after 13 cycles; certain atrial events are not sensed since falling in the post-ventricular atrial blanking;

COMMENTS

A ventricular arrhythmia episode is recorded when the device detects a minimum of 5 consecutive ventricular cycles with a minimum 25% acceleration over the previous cycle in VVI mode, or when an PVC is detected (ventricular activity not preceded by atrial activity in an interval of -31 to -300 ms in DDD and with no interval in the SafeR ADI mode) followed by 4 additional PVCs which are accelerated by more than 25% compared to the rate preceding the first PVC in DDD mode or the SafeR ADI mode.

This tracing highlights the difficult issue of recording bursts of non-sustained ventricular tachycardia in patients with pacemakers. In this patient without significant heart disease, it is likely that the introduction of beta-blocker therapy is sufficient without the need to raise the possibility of upgrading to an implantable defibrillator.

The recording of non-sustained ventricular tachycardia episodes in pacemaker-implanted patients is relatively common. Management varies depending on existing symptoms and the presence of heart disease which may lead to an upgrade to an implantable defibrillator.



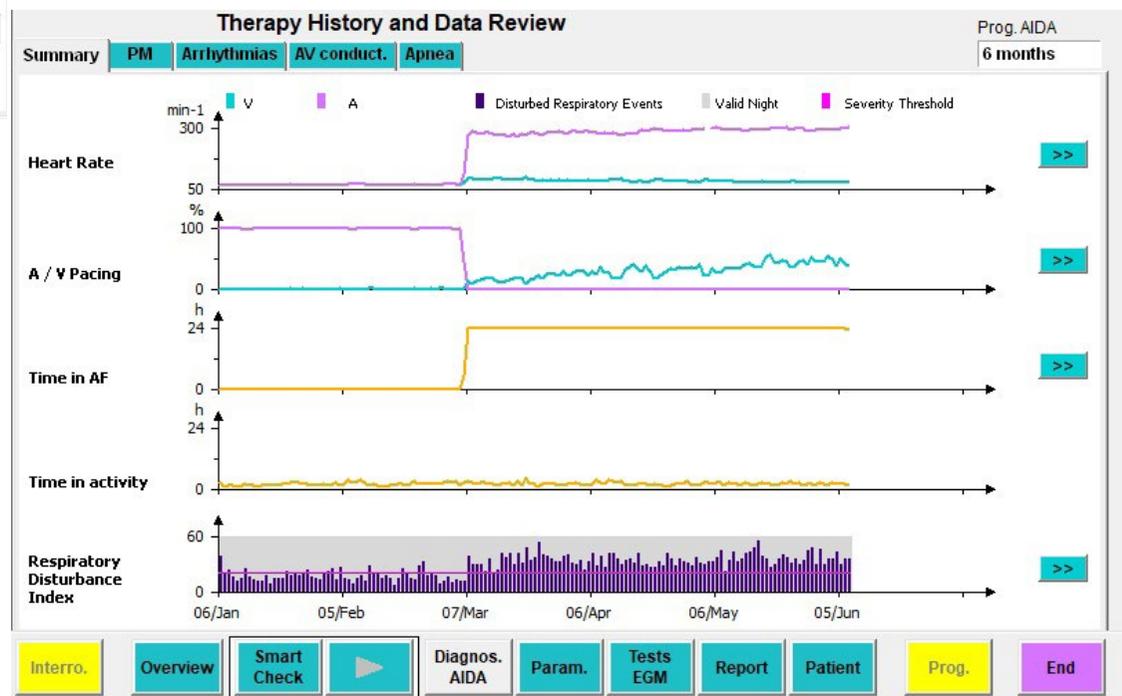
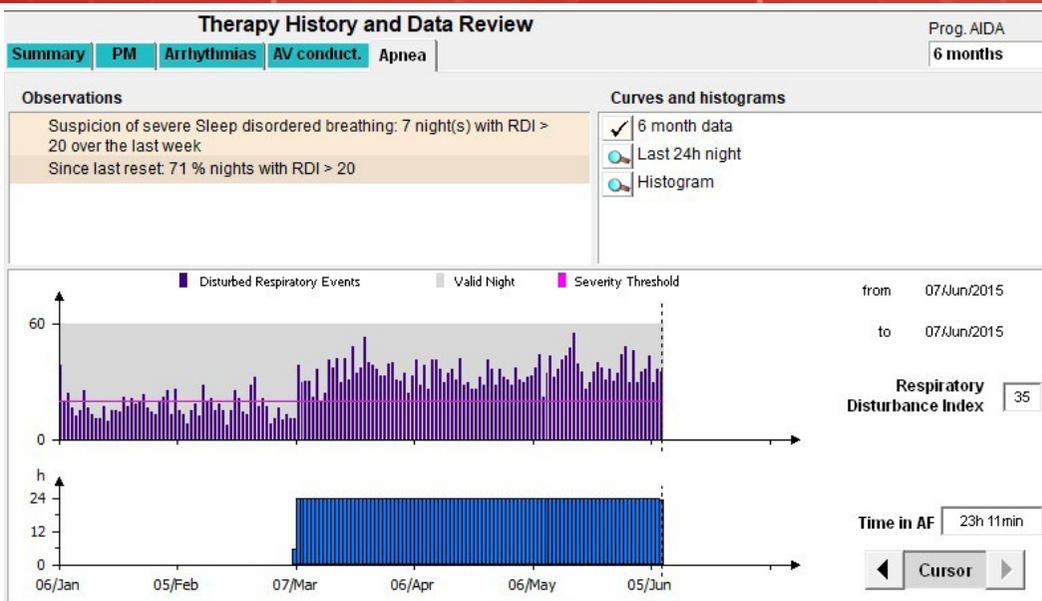
Patient

66-year-old woman implanted with KORA 100 DR dual-chamber pacemaker for ischemic cardiomyopathy and atrial disease; recording of atrial arrhythmia episodes in the device memory and suspicion of severe sleep respiratory disturbances in a patient not known to have nocturnal respiratory disorders;

Quiz

What is(are) the correct answer(s)?

- A. the prevalence of sleep apnea is increased in patients with hypertension
- B. the prevalence of sleep apnea is increased in patients with heart failure
- C. the prevalence of sleep apnea is increased in patients with AF
- D. the prevalence of sleep apnea is increased in patients with sinus dysfunction
- E. the prevalence of sleep apnea is increased in patients with atrial disease



TRACING

Interrogation of the device memory (AIDA) reveals a sharp increase in AF load (confirmed diagnosis by EGM recordings showing an AF becoming increasingly persistent) associated with a decrease in atrial pacing and a concomitant increase in apnea index that becomes permanently greater than 20, leading to suspect the presence of a severe respiratory sleep disorder;

COMMENTAIRES

Sleep apnea syndrome clearly represents a major public health issue because of its frequency and deleterious consequences. While polysomnographic remains the gold standard to diagnose sleep apnea syndrome, it is not widely used in clinical practice; sleep apnea therefore remains a disease that is often under diagnosed and therefore untreated. Prevalence is particularly high in the field of cardiovascular diseases with a direct and bilateral relationship between apnea and heart failure, conduction disorders and atrial arrhythmia. It is therefore clear that the population of patients with pacemakers is directly affected by this syndrome, confirmed by studies showing a prevalence which may exceed 50% of implanted patients.

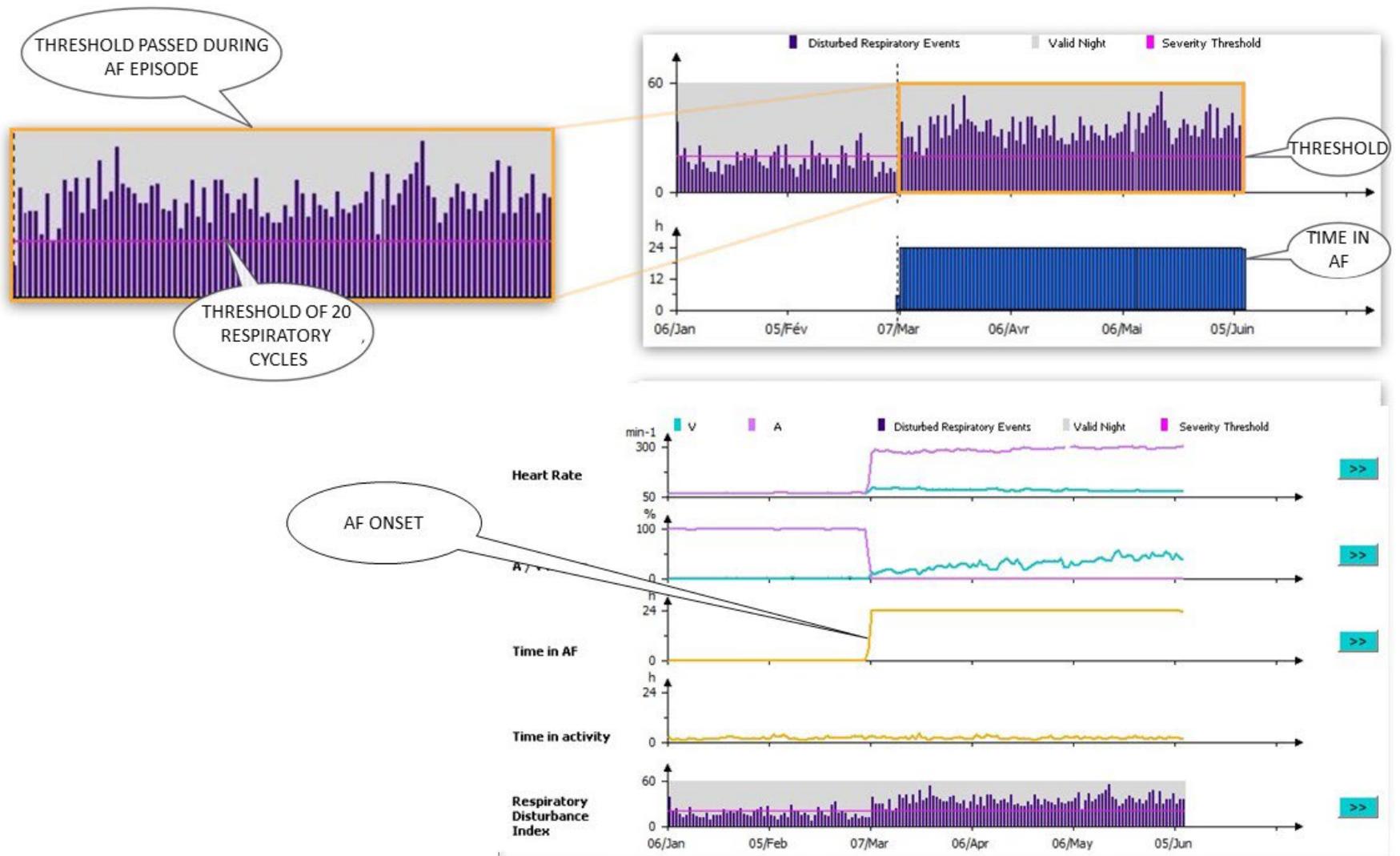
The MicroPort™ pacemakers have 2 rate-response sensors: an accelerometer and a minute ventilation sensor based on the transthoracic impedance measurement. Transthoracic impedance has 2: 1) static impedance in relation to the tissues traversed, which is measured at rest and in the absence of any breathing and of any heartbeat; its value is constant during the respiratory rhythm; this component is not used for the calculation of the minute ventilation and is eliminated by filtering; 2) dynamic impedance directly linked to the dynamics of respiratory movements; the variations of this impedance reproduce the dynamic variations of the pulmonary volume at the thoracic level; analysis of the variations of the period and amplitude of this signal allows the calculation of the minute ventilation which will be used to detect the presence of nocturnal ventilation disorders and to quantify the number of apneas and hypopneas.

A periodic transthoracic impedance assessment is performed with repeated measurements every 125 ms (sampling at 8 Hz). For each respiratory cycle (inspiration / expiration), the amplitude of this measurement varies with the thoracic movements, recording of a maximum value and a minimum value enabling to determine a period (in

relation to the duration of the respiratory cycle) and an amplitude (difference between minimum value and maximum value). These values are averaged over 8 respiratory cycles. Only respiratory cycles that are considered valid without detection of artifacts or disturbances are taken into account for the monitoring of respiratory disorders.

Respiratory arrest (apnea) corresponds to a period during sleep lasting more than 10 seconds and less than 60 seconds without a respiratory cycle (90 seconds in newest platforms). A reduction in ventilation (hypopnea) is characterized by a reduction in amplitude (50% decrease in the difference between minimum amplitude and maximum amplitude or 50% decrease in respiratory rate) for a duration of at least 10 seconds. The device establishes a respiratory disturbance index (RDI) which is defined by the sum of the respiratory arrests and the reductions in ventilation per hour of monitoring (apneas + hypopneas / hour). An RDI threshold greater than 20 suggests the presence of severe sleep apnea syndrome that must be confirmed by polysomnography. This index is measured during the hours defined as sleeping hours (nominal window of 5 consecutive hours 00h00-05h00). When a greater than normal number of cycles are considered invalid and are excluded during the night, the index is not measured (appears in white on the graph). The pacemaker provides the results of the nightly RDI over the last 6 months. Sleep apnea monitoring is only possible if the rate response is programmed to minute ventilation + accelerometer (MV + G) or minute ventilation (MV) only. Deactivating the rate response sensor automatically disables apnea tracking.

In this patient, analysis of the pacemaker data allowed suspecting a sleep apnea syndrome confirmed by polysomnography and enabled demonstrating the direct relationship between AF and increased severity of sleep disorders.





RATE SMOOTHING

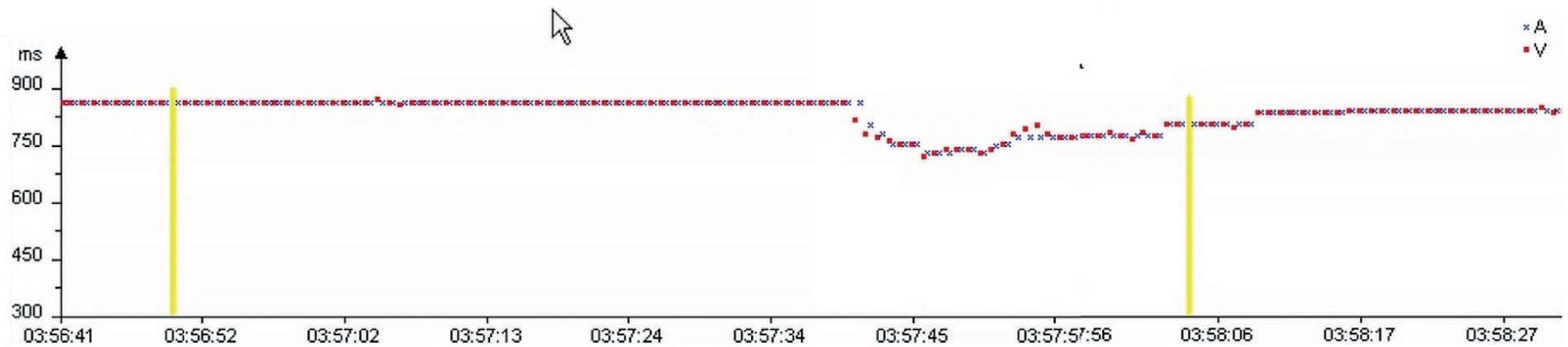
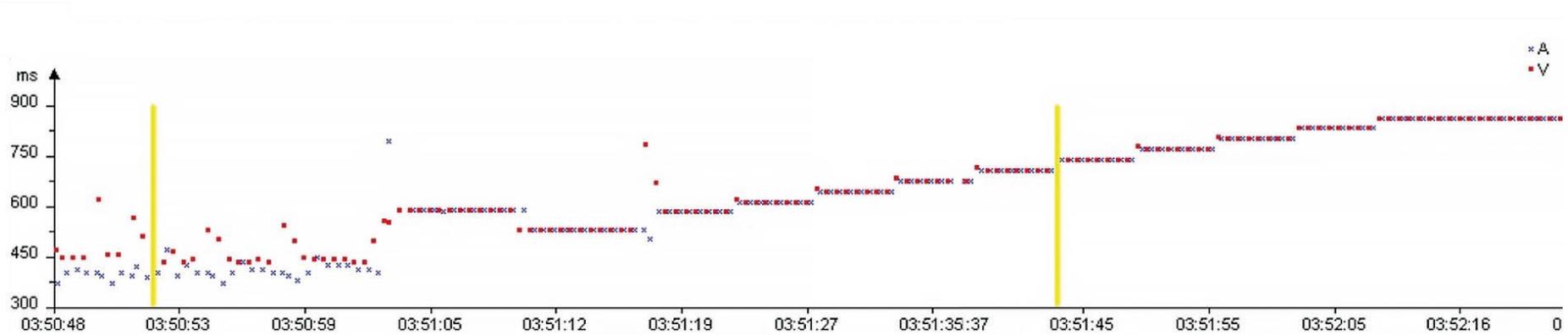
This algorithm acts as a frequency parachute when the frequency suddenly decreases in the atrium in double chamber modes, or in the ventricle in VVI or during a mode switch. This algorithm avoids abrupt sinus rate variations that can trigger atrial rhythm disorders in brady-tachycardia patients, for example. Frequency variations can also cause palpitations, which are dampened by the smoothing action.

The system continuously calculates the average of the current heart rate over a window of 8 cycles. When a sudden change in heartrate occurs, the device starts to pace from the calculated average interval plus a programmed interval (from 15 à 95ms corresponding to one of the four smoothing settings: very slow, slow, medium, fast). Every 8 cycles, this additional interval will be applied for the next 8 cycles, and so on until the programmed base frequency is reached as long as no spontaneous cycle occurs. In this case, the smoothing frequency will start again from the newly calculated average frequency.

The screenshot displays a configuration interface for a medical device. At the top, there are tabs for 'Pacing/Sensing', 'Brady', 'Remote', and 'Auto Implant Detect'. The main area is divided into several sections:

- MRI:** MRI Mode is set to 'Off'.
- Basic Functions:** Smoothing is set to 'Off' (highlighted in yellow), Mode Switch/Fallback rate is 'On' at '60 min-1', and Anti-PMT is set to 'Reprog'.
- Rate Response:** Rate response is set to 'No'.
- Prevention of A arrhythmia:** Overdrive, PAC pause suppression, and PAC acceleration are all set to 'Off'.
- Apnea:** Monitoring is 'Off' and Night period is '00:00-05:00'.
- Refractory period:** A dropdown menu is open, showing options: 'Off', 'Very slow', 'Slow', 'Medium', and 'Fast'. The 'Very slow' option is highlighted in yellow. The '150 ms' and '95 ms' values are visible next to the 'Off' and 'Very slow' options respectively.
- Preprogrammed Settings:** Includes 'Erase' and 'Save' buttons, a 'Name' field, and a list area.

Interval plot example of rate smoothing



AUTOMATIC AV DELAY

AV delay during Exercise

This function mimics the physiological behavior of the PR interval. On average, the PR interval shortens by 4 ms every 10 beats of sinus rate acceleration during exercise, although large individual variations are possible.

The shortening of the PR interval is based on a mechanical imperative: the fast-filling A wave shortens during exercise because of the increase in contraction velocity, which explains the concomitant shortening of the PR interval to continue to benefit from the longest possible ventricular filling without diastolic mitral regurgitation. The shortening of the AV delay of a pacemaker therefore attempts to mimic and respects this mechanical physiological law.

On electrophysiological level, since the AV delay is an atrial refractory period, shortening the AV delay allows the total atrial refractory period (AV delay + post-ventricular atrial refractory period) to be shortened when the atrial rate accelerates, which favors the detection of atrial arrhythmias in DDD mode. In MicroPort, it is true, the total atrial refractory period is already very short since there is no PVARP in sinus rhythm or in mode switch, but post-ventricular atrial blanking (which is generally 150 ms to cover a possible atrial ventricular far-field listening). Nevertheless, the shorter this total atrial refractory period, the better the device is able to diagnose rapid atrial rhythm disorders.

We remind you that with MicroPort, there is a true PVARP only after a ventricular extrasystole or after a lead test, a magnetic mode, an electrophysiology sequence, or a PMT interruption. The WARAD protects the ventricles in the event of atrial arrhythmia.

Pacing/Sensing
Brady
Remote
Auto Implant Detect

Basic Parameters

Mode DDD

Basic Rate 50 min-1

Max Rate 130 min-1

Hysteresis 0 %

AVD Rest/Exer 110 ms 80 ms

AVD Paced/Sensed Offset 30 ms

Accel. /AVD short. 0 %

Pacing/Sensing

	A	V
Sensitivity	0.6 mV	1.5 mV
Sensing Polarity	Bipolar	Bipolar
Autosensing	Monitor	Monitor
Amplitude	2.0 V	2.5 V
Width	0.35 ms	0.35 ms
Paced Polarity	Bipolar	Unipolar
Autothreshold	Monitoring	Monitoring
Amplitude Safety Margin	x2.0	x2.0
Min Amplitude	1.5 V	2.5 V
Safety Amplitude	3.5 V	3.5 V
Max Amplitude	5.0 V	5.0 V
Max Rate	110 min-1	100 min-1
Start Time	02:00	every 6h
Lead Polarity Switch	Off	Off

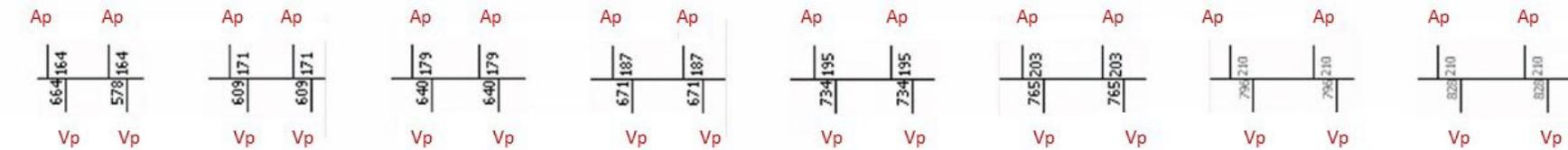
Preprogrammed Settings

Erase
Save

Name

First interrog. 14/Mar/2022 09:04

In our example, the programmed mode is DDD with a resting AV delay and an exercise AV delay programmed at 110 and 80 ms, applied to the programmed baseline and maximum frequency, respectively. In between, the applied AV delay value is interpolated in steps of 8 ms. The programmed values are for AV delays following a spontaneous P-wave (As). After a paced P-wave (Ap), a "AVD Paced/Sensed Offset" is added (30 ms in this example).



In this example, the AV delay value lengthens during deceleration of the atrial pacing rate until it maxes out at the programmed rest of AV delay at lower rate + Paced/Sensed offset value.

Paced/Sensed offset of the AV delay (= extension of AVD).

This algorithm intends to maintain the same atrio-ventricular mechanical sequence whether the atrium is sensed or paced, and the extension is therefore added to the AV delay after the spontaneous P-wave at the same frequency.

Its measurement is quite simple. In the event of intrinsic AV conduction, it is sufficient to record the EGM when the AV rhythm is totally spontaneous, and to measure the PR interval with the cursors placed on the As and Vs markers. Then the EGM is recorded when the atrium is paced at a rate just above the sinus rate and the Ap-Vs interval is measured. The difference between As-Vs and Ap-Vs results in the value of the "AVD paced/sensed offset" to be programmed.

In the event of AV block, the reference measurement is echographic; between the peak of the left ventricular diastolic filling A wave and the ventricular pacing artifact or closure of the mitral valve, perfectly identifiable events which limit intra- and interobserver measurement errors.

ANTI-PMT (PACEMAKER MEDIATED TACHYCARDIA) ALGORITHM

Detection Phase (8 cycles)

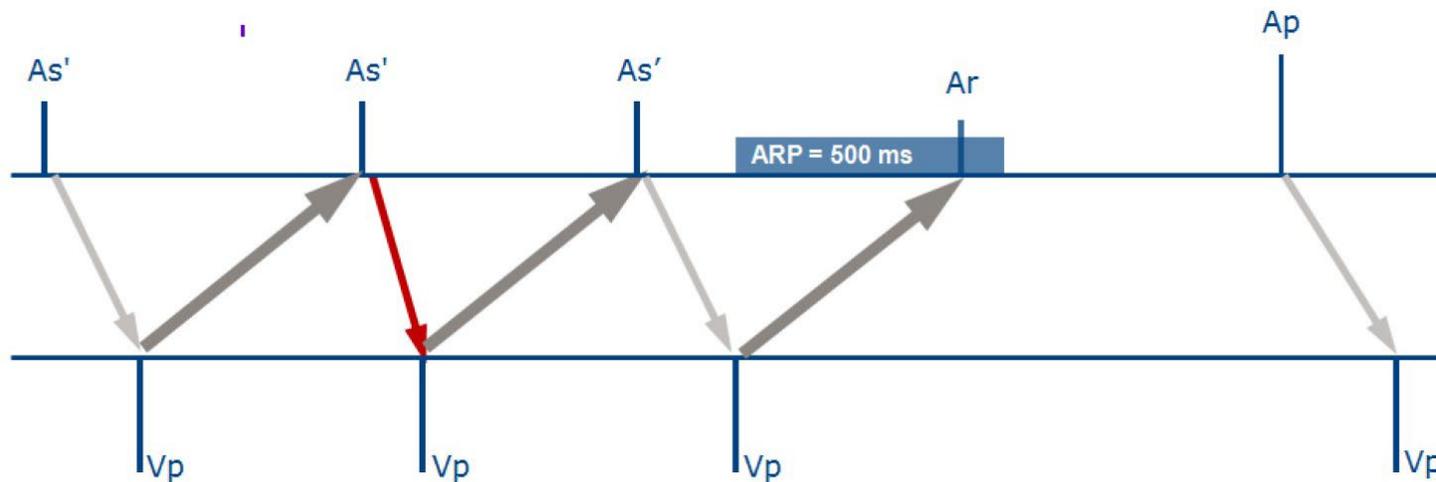
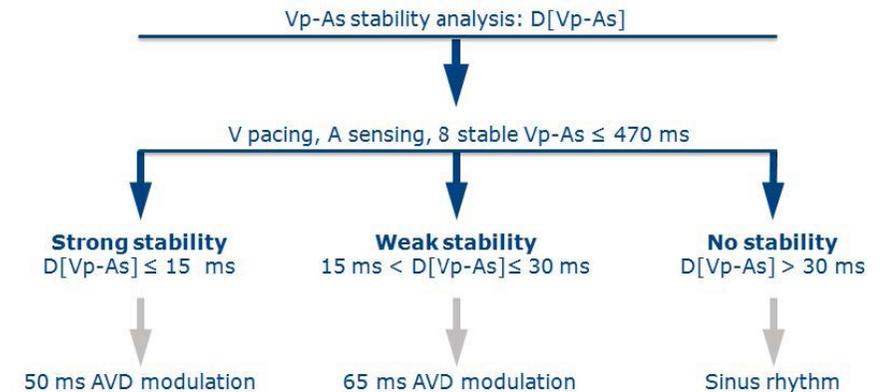
There is a suspicion of PMT when during eight cycles, the Vp-As intervals are stable (within 15 ms) and below 470 ms.

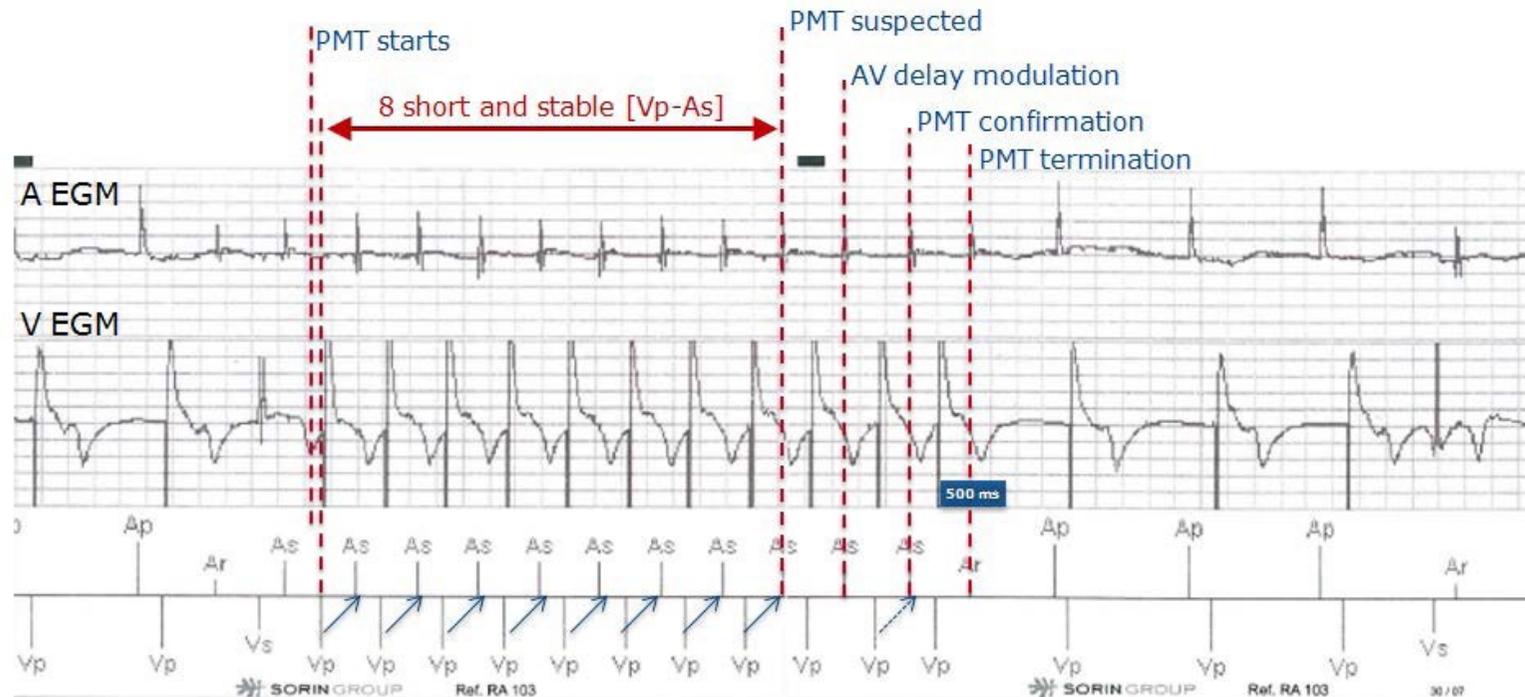
Confirmation Phase (2 cycles)

A duration of the AV delay is applied to a single cycle, when the Vp-As interval remains stable (within 15 ms), a change of the AV delay of 50 ms is triggered, and the Vp-As interval remains stable, an ARP of 500 ms is applied on the following cycle which terminates the PMT because the following retrograde atrial activities will be within the refractory period and trigger an AV delay and ventricular pacing. When the Vp-As interval remains stable between 15 and 31 ms, the applied AV changes 65 ms.

A short AV delays be applied to the following beat.

The PMT episode counted within the statistics.





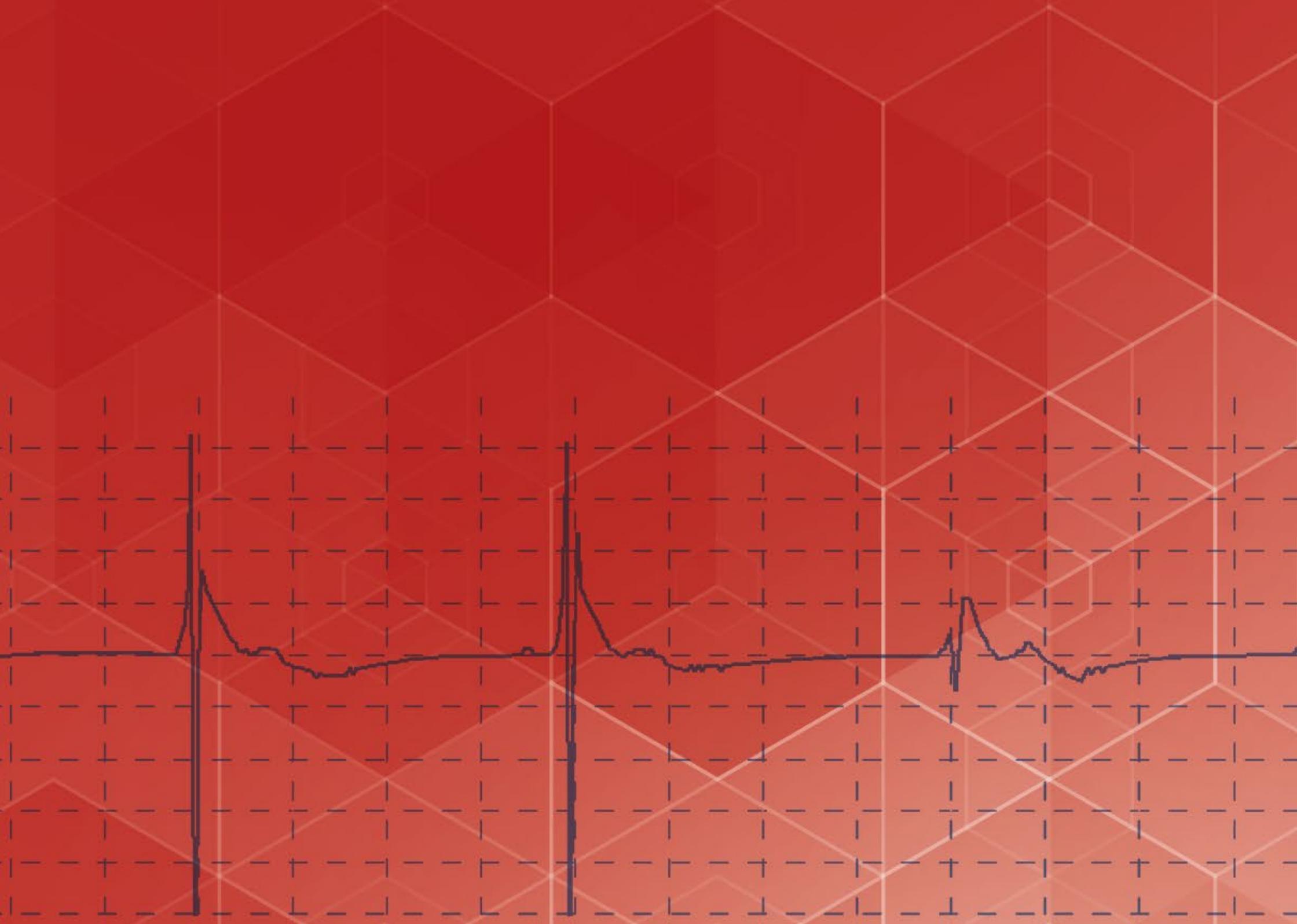
In this example, a PMT is initiated because an atrial extrasystole falls within the WARAD and does not initiate an AV delay. Spontaneous conduction occurs with a long PAC (Ar) - Vp interval which favors retrograde conduction that is seen outside the WARAD (As), with initiation of a stable PMT over 8 cycles. Indeed, the nodal conduction pathways have recovered during the long PR, which allows retrograde conduction after ventricular pacing. After 8 cycles, a 1-cycle modulation of the AVD lengthens the VV interval, and the PMT is confirmed because the retrograde P' wave results in a Vp-As interval that is identical and stable to that measured during the PMT (within 15 ms). A 500-ms refractory period is applied on the next cycle that breaks the PMT. A short AV delay is triggered on the next cycle. If it had been an autonomous atrial rhythm, the AV-delay change would have induced a shortening of the Vp-As time, and the PMT confirmation would not have been fulfilled.

The screenshot displays a pacemaker configuration interface with the following sections and settings:

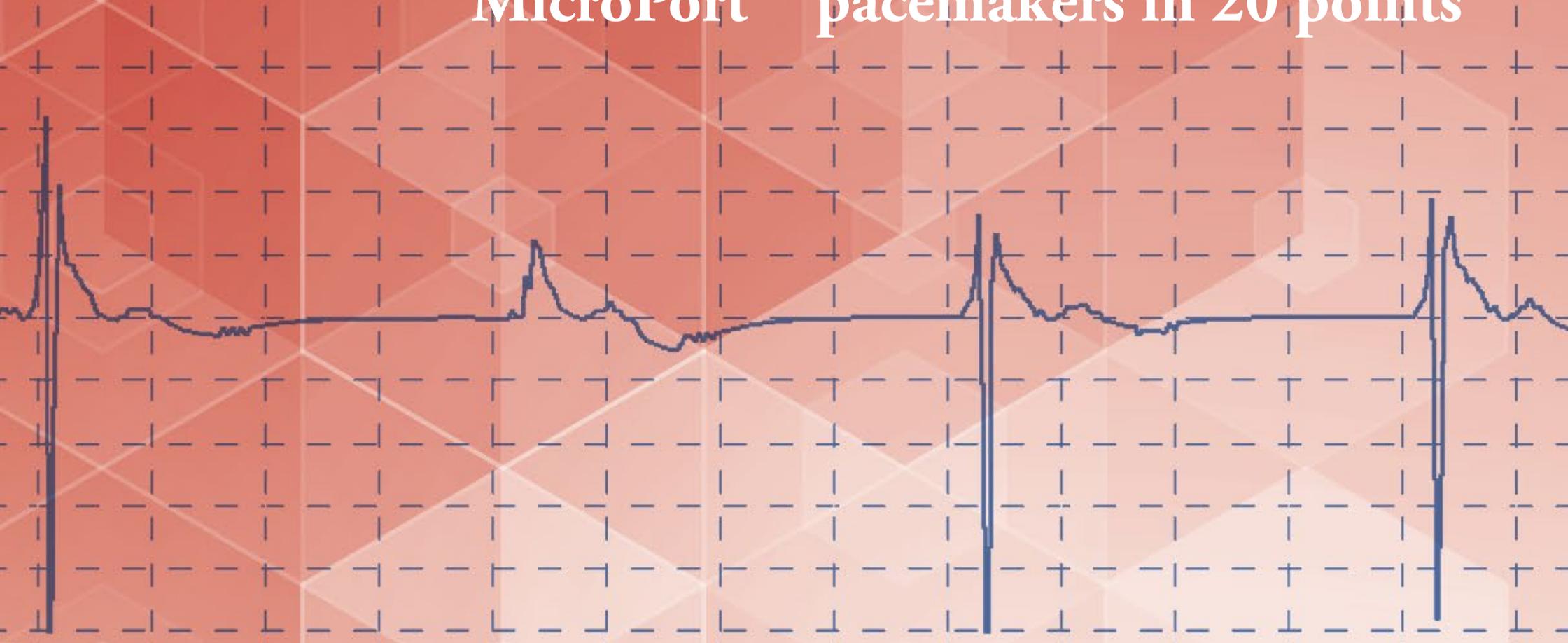
- Pacing/Sensing** (Active tab)
- Brady** (Inactive tab)
- Remote** (Inactive tab)
- Anti Inhibit Detect** (Inactive tab)
- MRI**: MRI Mode is **Off**.
- Basic Functions**:
 - Smoothing: **Off**
 - Mode Switch/Fallback rate: **On** (60 min⁻¹)
 - Anti-PMT: **Reprog** (highlighted in yellow)
 - Rate Response:
 - Rate response: **Learn**
 - Sensor: **Twin Trace**
 - MV Configuration: **A Bipolar**
- Refractory period**:
 - Post V Atrial Blanking: **150 ms**
 - Post R Atrial Blanking: **95 ms**
- SafeR : AAI->DDD criteria**:
 - AVB I switch: **Rest+Exer**
 - Long PR at rest: **350 ms**
 - Long PR at exercise: **250 ms**
 - Max pause: **3 s**
- Apnea**:
 - Monitoring: **On**
 - Night period: **00:00-05:00**
- Prevention of A arrhythmia**:
 - Overdrive: **Off**
 - PAC pause suppression: **Off**
 - PAC acceleration: **Off**
- Preprogrammed Settings**:
 - Erase (button)
 - Save (button)
 - Name: []

A long AV delay is the most common trigger of a PMT. A solution is to shorten the AV delay until PMTs stop occurring. However, in our example the permanent shortening of the AV delay would not have any influence since it was the long PR interval after a premature atrial complex which triggered the PMT.

When the anti-PMT algorithm is programmed "Reprog" (default setting except for the US), the programmed AV delay at rest and at exercise are shortened when more than 10 PMTs per day are observed, until the limits of 125 and 80 ms, respectively. In this case, interrogation, the following message is displayed "the AV delay is reprogrammed automatically by the device". When an elevated number of PMTs is observed in the statistics, a trigger should be sought. Common triggers are: atrial sensing or capture issues, lead noise, atrial or ventricular premature complexes, etc... All causes of AV dissociation may favour retrograde conduction beyond refractory periods and therefore trigger PMT.



MicroPort™ pacemakers in 20 points



1

Device dimensions

Single-chamber Kora 100/250 Reply 200, Eno, Teo, Oto SR: 7.5 cm³

Dual-chamber Kora 100/250 DR: 8 cm³

Single-Chamber Alizea, Borea, Celea: 10,5 cm³

Dual-chamber Alizea, Borea, Celea: 11 cm³

2

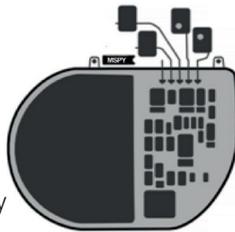
Battery type: LiS 3150 MP Lithium

Manganese dioxide (3.2V, 1.2 Ah)

3

Depletion and longevity criteria

Values expressed: magnet rate; battery and residual longevity



impedance/voltage

BOS (Beginning Of Service): 3.20 V without RMS / 3.10 V with RMS - 96 min⁻¹

RRT (Recommended Replacement Time): 2.70 V without RMS / 2.63 V with RMS - 80 min⁻¹

EOS (End Of Service): 2.50 V - 70 min⁻¹

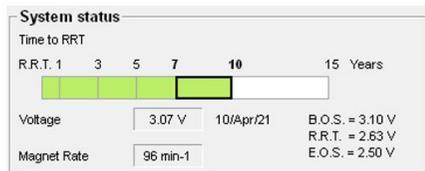
From ERI to end-of-service (complete depletion), the pacemaker automatically adjusts to VVI mode, with rate at 70 min⁻¹, programmed pacing and sensing parameters, rate response Off and rate smoothing.

Reprogramming is possible; however, at the next daily battery impedance measurement, the device switches back to the parameters described above.

KORA



ALIZEA



Residual longevity (estimated residual longevity indicator)

Residual longevity is the estimated remaining service time of the device up to the RRT (Recommended Replacement Time). This estimate is calculated based on the internal battery impedance, leads measurements, the statistics and the programmed parameters. The residual longevity is automatically recalculated after each change in programming.

The typical residual longevity of the device is displayed as follows:

- If the typical* residual longevity is > 10 years, "the typical* residual longevity" is displayed and the corresponding text field is grey:

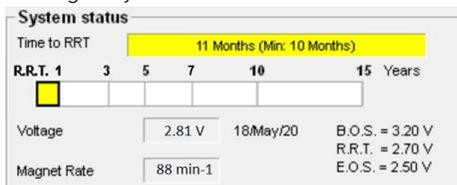


- If the typical* and minimal** residual longevity are between 3 months and 3 years, "the typical* residual longevity (minimal** residual longevity)" are displayed and:

- a) the corresponding text field is grey, if the estimated minimal residual longevity is > 12 months.



- b) the corresponding text field is yellow, if the estimated minimal residual longevity is ≤ 12 months. A warning will be displayed: "Under the current conditions of use, minimal residual longevity ≤ 12 months".



- If the typical* residual longevity is < 3 months, "< 3 months" is displayed and the corresponding text field is orange.



- If the RTT is reached, "The RRT has been reached" is displayed and the corresponding text field is red



"N/A" is displayed in the field, the background is grey if less than 5 minutes statistics are available (i.e. the first interrogation at implantation, device reset/reinitialization), or if the lead impedance is abnormal (<200 and ≥ 3000 Ω).

* The typical residual longevity is an estimate taking into account typical battery discharge profiles.

** The minimal residual longevity is an estimate taking into account the worst battery discharge profiles.

4

Magnet rate

Beginning of service: 96 min-1

RRT (Recommended Replacement Time): 80 min-1

End of service: 70 min-1

Magnet response programming specificities:

Phase 1: application of the magnet (as long as the magnet is applied)

- Rate = Magnet rate
- Mode: D00 or V00
- Pacing: 5 V / 0.5 ms / Rest AV delay

Phase 2 (Removal of the magnet): Capture test (6 cycles)

- Rate = Magnet rate
- D00 or V00
- Pacing: programmed amplitude and pulse duration / AV delay = 95 ms

Phase 3 (Removal of the magnet continued): Range test (2 cycles)

- Rate = programmed basic rate
- Mode: D00 or V00
- Pacing: programmed pulse amplitude and duration /programmed AV delay

5

All conventional modes are available.

6

Specific mode favoring intrinsic conduction: Safer mode

ADI(R) <=> DDD(R) switching criteria: different criteria induce switching to DDD mode: pause (programmable pause without ventricular beats/VS), AVB III (2 consecutive atrial cycles without ventricular beats/VS), AVB II (3 out of 12 cycles without ventricular beats/VS), AVB I (patient PR > programmed long PR, 6 consecutive intervals, possibility of programming for activation during exercise or rest + exercise).

DDD(R) <=> ADI(R) switching criteria: when the pacemaker is operating in DDD mode, it searches for the presence of an underlying intrinsic rhythm. The pacemaker switches back to ADI under 3 circumstances: after 12 consecutive sensed ventricular events; automatically after 100 paced ventricular cycles or after the sustained switching period which stops every morning at 8 o'clock. The device switches and remains in DDD mode (overnight until 8 am) in case of persistent AV block: more than 45 AVB

episodes per 24 hours, more than 15 AVB episodes per 24 hours during 3 consecutive days, over 50% of the time spent in DDD during one hour

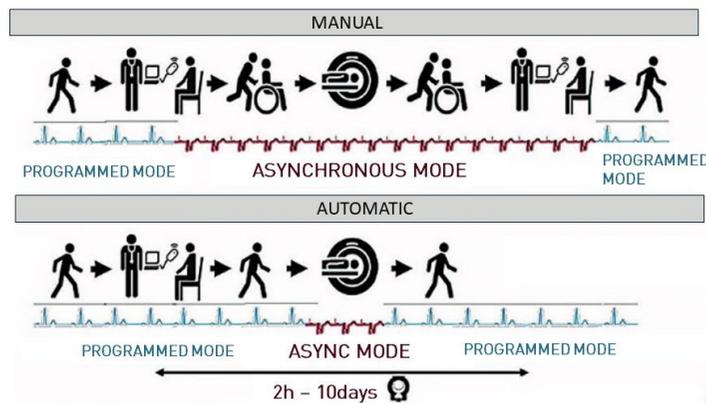


7

MRI Mode

The MRI mode is a mode (D00, V00 or 000) that is triggered either manually or upon automatic detection of a strong magnetic field. The operating period of the MRI mode can be between 2 to 10 days hours depending on the programming. If the setting is on AUTO, the device recognizes the magnetic field when undergoing the MRI and automatically switches to MRI mode. Available MRI pacing modes are: D00, V00, 000.

MRI	
MRI Mode	Auto
MRI Monitoring Period	10 days
MRI Pacing Mode	D00
MRI Pacing Rate	70 min ⁻¹



8

Ventricular pacing: Ventricular Autothreshold

Ventricular Autothreshold on Auto: regular measurements of the ventricular pacing threshold + automatic adjustment of the programming; Ventricular Autothreshold on Monitor: regular measurements of the ventricular pacing threshold but without adjustment of the programming.

Threshold routinely performed every 6 hours; capture control based on the analysis of the evoked response; 4 threshold measurements per day with adjustment for the ensuing 6 hours; automatic adjustment of the amplitude to twice* the threshold value (safety margin of 100%) within the limit of a programmable minimum value (1.5, 2, 2.5, 3 or 3.5 V)

* programmable on newest platforms

9

Atrial pacing: Atrial Autothreshold

Atrial Autothreshold is available on the latest MicroPort™ pacemaker platforms.

Threshold systematically performed at 1 a.m. or 2 a.m.; the presence of effective atrial capture is suggested in the absence of intrinsic atrial activation or in relation to the presence of 1:1 ventricular conduction; 1 measurement performed once daily, at night time with adjustment for the next 24 hours; automatic adjustment of the amplitude by applying the amplitude safety margin: threshold x 2 by default, or the programmed Minimum atrial amplitude if higher..

10

Sensing and sensitivity

Atrial and ventricular sensing can either be programmed to Fixed or Autosensing.

It is possible to program Autosensing on 1) Monitor allows to measure the amplitudes of the P waves and R waves without adjustment of the sensitivity settings which remains fixed; 2) Auto which allows to measure the P waves and R waves with automatic adjustment of the sensitivities: the amplitude of the signals is averaged over 8 consecutive cycles and the sensitivity is programmed to a third of this average value.

11

Refractory periods

Following atrial pacing, a non-programmable 30 ms refractory period is triggered at the ventricular stage. If ventricular sensing occurs between the end of this refractory period and the end of the safety window (95 ms after the atrial stimulus), ventricular pacing is delivered at the end of the safety window.

Following atrial sensing or pacing, another non-programmable relative refractory period is triggered at the atrial stage. Its duration is dynamic and is calculated according to the atrial rate. Its purpose is to detect the acceleration of the atrial rate (hence its name: WARAD, Window of Atrial Rate Acceleration Detection). There is no PVARP on MicroPort pacemakers. Following the sensing of a ventricular event considered as a PVC, a relative refractory period (the ARP) is triggered at the atrial stage. Its duration is 500 ms.

12

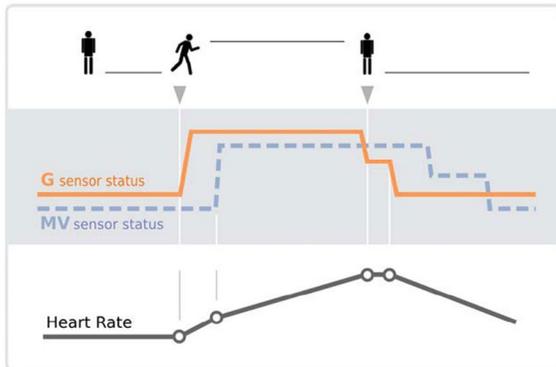
Diagnosis and termination of pacemaker-mediated tachycardias

The «Anti-PMT» algorithm is always active in atrial tracking mode (non-programmable). Initial 8-cycle detection phase: the device measures the retrograde conduction time (Vp-As) and suspects a PMT if the Vp-As intervals are stable (within 30 ms) and short (< 470 ms). 2 -4 cycle confirmation phase: the device modulates the AV delay to verify the stability of the Vp-As interval. Termination of the PMT by prolongation of the relative atrial refractory period. If the anti-PMT option is set to "REPROG", the rest and exercise AV delays are automatically shortened. The "Anti PMT" can be switched OFF in ALIZEA, BOREA, CELEA pacemakers.

13

Rate response

MicroPort pacemakers are equipped with 2 sensors that can work together or separately: an accelerometer and a minute ventilation sensor (measurement of transthoracic impedance). When used simultaneously, the pacing rate is first guided by the accelerometer (better reactivity at the start of exertion) followed by the minute ventilation sensor in the middle and at the end of exertion.



14

Functioning of the atrial arrhythmia fallback

The fallback function has three distinct phases: 1) the suspicion phase: as soon as a ventricular cycle with suspicion of atrial arrhythmia is detected, the fallback algorithm begins the analysis over 32 ventricular cycles. Atrial arrhythmia is confirmed if 28 or more ventricular cycles are in suspicion over the last 32 ventricular cycles (primary criterion) or if 18 or more ventricular cycles are in suspicion for each of the last two blocks of 32 ventricular cycles (secondary criterion); 2) the dissociation phase: once one of the fallback criteria has been reached, the pacing mode switches from a synchronous mode to an asynchronous mode (DDI); 3) the reassociation phase: as soon as the atrial arrhythmia ceases and sinus rhythm resumes, the ventricular pacing rate is gradually adapted to reach the sinus rhythm. A-V reassociation occurs when the atrial and ventricular rates are slower than 110 min⁻¹.

210

15

2:1 Flutter management

No specific algorithm; when a 2:1 flutter occurs, it is necessary to shorten the duration of the post-ventricular atrial blanking.

16

Prevention of atrial arrhythmias

3 algorithms are available

Sinus rhythm Overdrive: the pacing rate is increased to «overdrive» intrinsic atrial activation. Extrasystolic Pause Suppression and Acceleration on PAC: after a PAC, the pacing rate is increased to avoid the succession of short cycle - long cycle sequences.

17

Wireless interrogation

Wireless technology (Bluetooth) is available for the implantations/follow-ups and the Remote Monitoring System.

18

Memory capacity

Maximum recording time of EGMs: approximately 22 minutes with A and V sampling rate of 512 Hz, 22 stored episodes, with annotated markers, synchronized with the intracardiac EGM.

19

Remote monitoring

SmartView Connect on newer platforms (e.g. Alizea) provides daily connectivity with Bluetooth low energy and wireless transmission with 4G. SmartView Hotspot system is based on the principle of remote pacemaker interrogation using a telemetry device (placed onto the pacemaker) linked to a transmitter connected to the internet by the GSM telephone network.



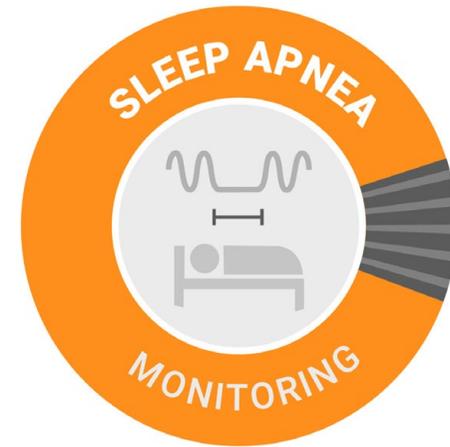


The Smartview website is intuitive and allows you to view Brady (and Tachy) report transmissions. Reports are optimized for easy reading without notification overload.

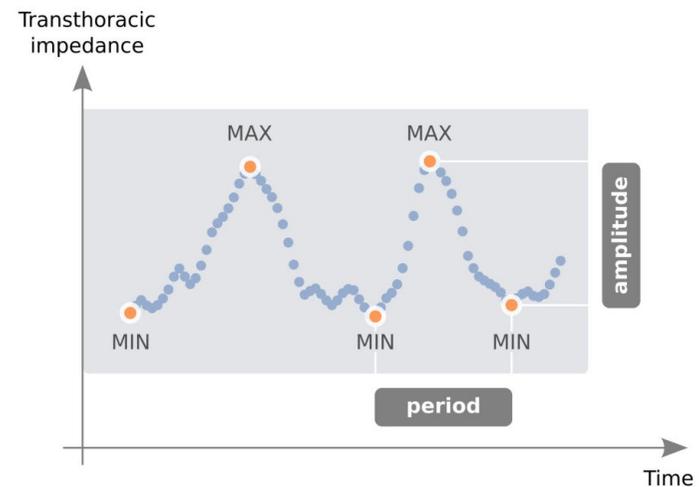


20

Sleep apnea monitoring

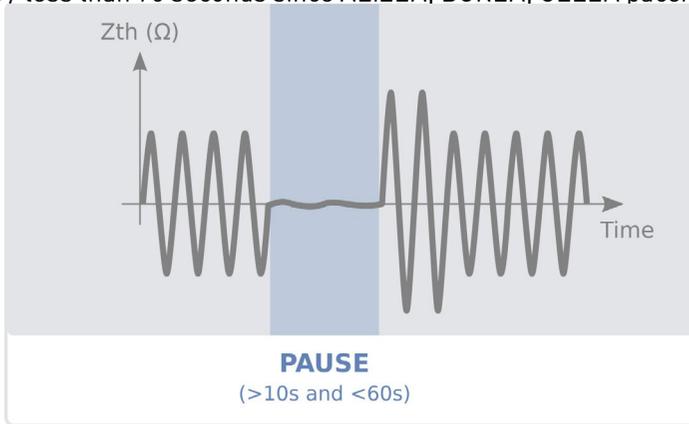


Sleep apnea monitoring: transthoracic impedance data are measured using the MV sensor.

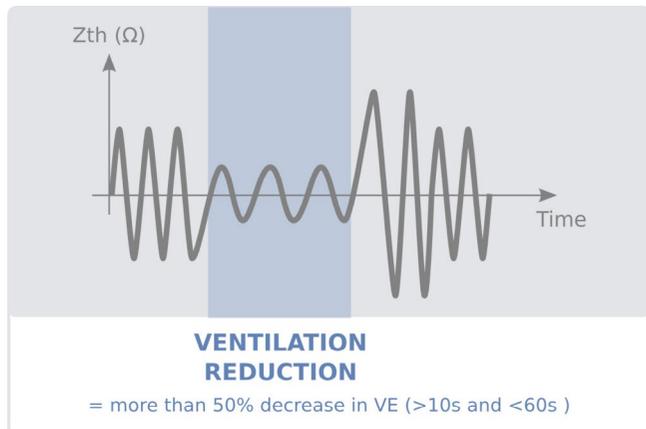


Sequences of respiratory cycles are analyzed to detect, count and display abnormal breathing events during the night (programmable monitoring period). Two types of respiratory events are measured:

- Respiration pauses: when the interval between two breathing cycles is longer than 10 seconds and less than 60 seconds. for ENO, TEO, OTO pacemakers and previous generations / less than 90 seconds since ALIZEA, BOREA, CELEA pacemakers

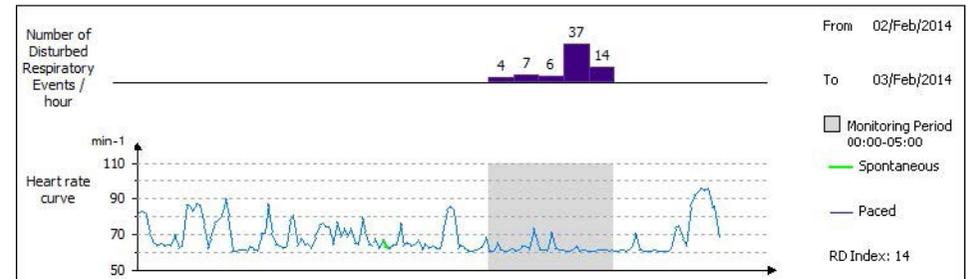
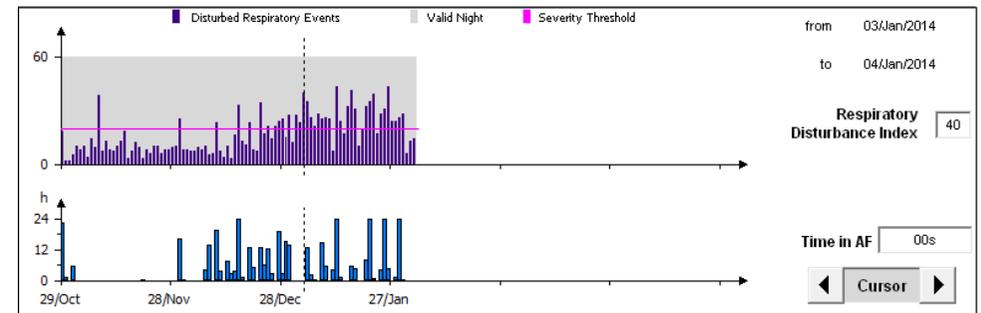


- Respiration reductions: when the Ventilation (VE, defined as the amplitude of a breathing cycle divided by its period) is reduced by 50% or more compared to the average VE over the 8 previous cycles, for more than 10 seconds and less than 60 seconds. for Eno, Teo, Oto pacemakers and previous generations / less than 90 seconds since Alizea, Borea, Celea pacemakers



A Respiratory Disturbance Index (RDI) is calculated by dividing the number of respiratory events by the number of hours of monitoring (5 hours). A severity threshold is used to indicate the risk of severe (sleep disordered breathing, sleep apnea syndrome) of the patient.

Sleep apnea monitoring is automatically activated during the first interrogation of the pacemaker (after the automatic implantation detection).





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Stimuprat Editions
4 avenue Neil Armstrong
Bâtiment Le Mermoz
33700 Mérignac - France
Email : contact@stimuprat.com

www.cardiocases.com
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